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No. 99-1426

IN THE

Supreme Court of the United States

AMERICAN TRUCKING ASSOCIATIONS, INC., CHAMBER OF COMMERCE OF THE UNITED STATES, *ET AL.*,*

Cross-Petitioners,

v.

CAROL M. BROWNER, ADMINISTRATOR OF THE ENVIRONMENTAL PROTECTION AGENCY, *ET AL.*,

Cross-Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

BRIEF FOR CROSS-PETITIONERS

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QUESTION PRESENTED

Whether the Clean Air Act requires that the Environmental Protection Agency must, in setting nationwide air-quality standards, ignore all factors other than health effects relating to pollutants in the air, given that consideration of such factors would permit both the Agency and reviewing courts to avoid confronting constitutional nondelegation issues.

PARTIES TO THE PROCEEDINGS

Cross-Petitioners are: American Trucking Associations, Inc., Chamber of Commerce of the United States, National Coalition of Petroleum Retailers, Burns Motor Freight, Inc., Garner Trucking, Inc., Genic Trucking Line, Inc., National Automobile Dealers Association, National Association of Manufacturers, National Small Business United, The American Portland Cement Alliance, The Glouster Company, Inc., Non-Ferrous Founders' Society, Equipment Manufacturers Institute, American Farm Bureau Federation, and American Road and Transportation Builders Association.

None of these cross-petitioners has any parent corporations, and no publicly traded company owns 10 percent or more of any of these cross-petitioners' stock.

Respondents are: Carol M. Browner, the Administrator of the Environmental Protection Agency, and the Environmental Protection Agency.

The following additional entities participated as parties in the court of appeals: Alliance of Automobile Manufacturers (formerly American Automobile Manufacturers Association), American Chemistry Council (formerly Chemical Manufacturers Association), American Forest and Paper Association, American Iron and Steel Institute, American Lung Association, American Petroleum Association, American Public Power Association, Appalachian Power Company, Atlantic City Electric Company, Baltimore Gas and Electric Company, James Bassage, Carolina Power & Light Company, Centerior Energy Corporation, Central and South West Services, Inc., Central Hudson Gas & Electric Corporation, Central Illinois Light Company, Central Illinois Public Service Company, Central Power & Light Company, CINergy Corporation, Citizens for Balanced Transportation, Cleveland Electric Company, Columbus Southern Power Company, ComEd Company, Consumers Energy Company, Dayton

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Virginia, West Virginia Chamber of Commerce, and Wisconsin Electric Power Company.

The following participated as *amici curiae* in the court of appeals: Representative Tom Bliley, Senator Orrin G. Hatch, Connecticut, New Hampshire, New York, and Vermont.

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INTRODUCTION

Two decades ago, the D.C. Circuit ruled in *Lead Industries Ass'n v. EPA*, 647 F.2d 1130, 1148, 1153-54 (D.C. Cir. 1980), that the Environmental Protection Agency ("EPA" or "the Agency") must ignore all factors "other than health effects relating to pollutants in the air" in setting National Ambient Air Quality Standards ("NAAQS"). Pet. App. 15a (internal quotation omitted). That decision was wrong when decided and remains wrong to this day. The text of Clean Air Act ("CAA" or "Act") section 109(b)(1), a host of surrounding statutory provisions, and the Act's overall purposes all belie the notion that Congress intended to prohibit EPA from weighing *all* relevant factors in setting air-quality standards. Now, the same erroneous *Lead Industries* interpretation threatens to do more harm than good by apparently sanctioning new ozone ("O_3") and particulate matter ("PM") standards that EPA must concede (ozone) or that quite possibly (PM) have costs that outweigh their predicted health benefits.

The court below invalidated both of EPA's standards on constitutional nondelegation grounds, but only because it believed *Lead Industries* precluded EPA from setting standards based on a commonsense weighing of benefits and costs. Under *Lead Industries*, that decision was surely correct. But this Court need not reach constitutional nondelegation issues at all if it rejects *Lead Industries* and interprets the Act as contemplating the weighing of various pros and cons, including the supposed "non-health" factors presently embargoed under *Lead Industries*. Besides being supported by the statutory text, that outcome will further Congress' aim of protecting "public health" and promote reasoned EPA decisionmaking, while also facilitating effective Executive Branch and Congressional oversight of EPA's NAAQS under Executive Order 12,866 and recently-enacted statutory provisions.

OPINIONS AND ORDERS BELOW

The final EPA rules on review are reported at 62 Fed. Reg. 38,652 and 62 Fed. Reg. 38,856. The opinion of the court of appeals (Appendix to the Government's Petition ("Pet. App.") 1a-69a) is reported at 175 F.3d 1027. The opinions on the petitions for rehearing (Pet. App. 70a-101a) are reported at 195 F.3d 4.

EPA's rules and Regulatory Impact Statement have been lodged with the clerk. The other record materials cited herein may be found in the D.C. Circuit joint appendices for the ozone and PM cases ("OJA" and "PMJA," respectively).

JURISDICTION

The court of appeals entered its judgment on May 14, 1999. On October 29, 1999, timely petitions for panel rehearing were granted in part and denied in part, with suggestions for *en banc* rehearing denied in their entirety. The Government's petition for *certiorari* was timely filed on January 28, 2000, and the conditional cross-petition was timely filed on February 28, 2000. Supreme Court Rule 12.5 and 28 U.S.C. § 1254(1) provide the basis for jurisdiction.

PERTINENT CONSTITUTIONAL AND STATUTORY PROVISIONS

The following statutory and regulatory provisions are central to this case: the Clean Air Act, the Unfunded Mandates Reform Act, and Executive Order 12,866, relevant portions of which are set forth in the Appendix to this brief.

STATEMENT OF THE CASE

A. The Clean Air Act

This case requires the Court to construe for the first time Clean Air Act section 109, the core provision of the Nation's air pollution control program. CAA § 109, 42 U.S.C. § 7409. Under section 109, EPA must set National Ambient Air Quality Standards for the "criteria" pollutants listed under section

108(a)(1) of the Act, 42 U.S.C. § 7408(a)(1). Once EPA sets a NAAQS for a pollutant, the Act's Title I requires that all States enforce that NAAQS against the stationary emission sources within their borders. *See* CAA §§ 110, 171 *et seq.*, 42 U.S.C. §§ 7410, 7501 *et seq*. In addition, the NAAQS levels set by EPA heavily influence the setting of mobile source emission standards by EPA (and certain States) consistent with the Act's Title II. *See* CAA § 201 *et seq.*, 42 U.S.C. § 7521 *et seq*. These stationary sources include essentially all businesses, large and small, plus facilities operated by federal, State, and local governments. Mobile sources include, not just cars, trucks, trains, and airplanes, but also smaller emission sources, including boats, snowmobiles, and even lawn mowers. The NAAQS levels chosen by EPA, more so than any other federal regulatory decisions, pervasively impact the Nation's economy.

NAAQS are formulated by a lengthy process consisting of a series of discrete steps. EPA first develops an "air quality" "criteria document" for "each air pollutant . . . emissions of which . . . cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare," and which "results from numerous and diverse mobile or stationary sources." CAA § 108(a), 42 U.S.C. § 7408(a). After these criteria documents are reviewed by a scientific advisory committee established by section 109(d) of the Act, known as the Clean Air Scientific Advisory Committee or "CASAC," EPA proposes primary and secondary NAAQS, and these also are reviewed by CASAC. *See* CAA § 109(d), 42 U.S.C. § 7409(d). The primary NAAQS established by EPA must be set at levels "requisite to protect the *public health*" with "an adequate margin of safety." CAA § 109(b)(1), 42 U.S.C. § 7409(b)(1) (emphasis added). The secondary NAAQS must be set at levels "requisite to protect the *public welfare*." CAA § 109(b)(2), 42 U.S.C. § 7409(b)(2) (emphasis added).

Following promulgation of a NAAQS, EPA designates every geographic area in the nation (known as an "air quality

control region") as "attainment," "nonattainment," or "unclassifiable." CAA § 107(d), 42 U.S.C. § 7407(d). Each nonattainment area is then "classified" based on "factors such as the severity of nonattainment in such area and the availability and feasibility of . . . pollution control measures" for the area, and then, based on that classification, it is assigned an attainment date. *See* CAA § 172(a)(1, 2), 42 U.S.C. § 7502(a)(1, 2) ("Subpart 1"). Primary responsibility for meeting the attainment deadlines falls to the States, through the adoption and enforcement of State Implementation Plans ("SIPs"). *See* CAA § 110(a), 42 U.S.C. § 7410(a). Additionally, the 1990 amendments to the Act establish a specific plan directed at reducing ozone levels nationwide and eventually solving the intractable nonattainment problems for that pollutant that have persisted since the setting of the first NAAQS in 1971. Under that statutory plan, each ozone nonattainment area is assigned a classification based on the extent of its noncompliance with the ozone air-quality standards set by EPA in 1979, as well as a specific attainment date based on those classifications. *See* CAA § 181(a)(1), 42 U.S.C. § 7511(a)(1) ("Subpart 2").

B. The 1996 Rulemakings

In the early 1990s, EPA initiated proceedings to reconsider the NAAQS for ozone, originally set in 1971 and revised in 1979, and PM, originally set in 1971 and revised in 1987.

1. The Ozone Rulemaking

Ground-level ozone, often called smog, is formed through the reaction of volatile organic compounds ("VOCs") and oxides of nitrogen ("NOx") in the air, with the highest concentrations usually occurring during sunny, hot summer days. *See* 62 Fed. Reg. 38,856, 38,858 (July 18, 1997). Ozone levels are enhanced by human activity, but ozone also occurs naturally since both NOx (a product of burning) and VOCs (compounds emitted by vegetation) are present in nature.

According to EPA, peak background (*i.e.*, natural) levels of ozone generally range from 0.3 to 0.5 parts per million ("ppm"), and vary from region to region. *See* OJA 1830 (EPA's Ozone Staff Paper).

Elevated ozone levels are associated with various respiratory problems (ranging from discomfort to severe respiratory constriction) that can compound asthma and other lung ailments. EPA first addressed ozone in 1971 when it set a one-hour photochemical oxidant NAAQS at a level of 0.08 ppm, not to be exceeded more than once annually in each air quality control region. *See* 36 Fed. Reg. 8,186 (Apr. 30, 1971). While technically covering a broader category of compounds, compliance with the photochemical oxidant standard was judged by measuring ozone alone. States were required to meet this standard by 1975, but as of 1977, most regions of the country were far from compliance. *See* National Research Council, RETHINKING THE OZONE PROBLEM IN URBAN & REGIONAL AIR POLLUTION 4 (1991) ("RETHINKING OZONE"). In 1979, EPA partially responded by reevaluating the health evidence on which the original standard had been based and revising the maximum one-hour reading (now renamed the ozone NAAQS) upward to 0.12 ppm. *See* 44 Fed. Reg. 8,202 (Feb. 8, 1979). Congress also extended the deadline for compliance until 1982 for most areas, and until 1987 for areas not expected to be able to meet the 1982 deadline. *See* RETHINKING OZONE at 4. Ozone levels declined significantly after 1979, but most large metropolitan areas were still not in NAAQS compliance by 1990. *See* OJA 1823 (Ozone Staff Paper); RETHINKING OZONE at 4; Pet. App. 32a. Accordingly, Congress in the 1990 Amendments established the current Subpart 2 attainment schedule, which sets varying compliance deadlines, extending to 2010. *See* CAA § 181(a)(1), 42 U.S.C. § 7511(a)(1); Pet. App. 32a.

In 1992, EPA began its periodic, five-year review of the ozone NAAQS by updating the section 108 ozone air quality

criteria ("the Criteria Document"). *See* 57 Fed. Reg. 38,832 (Aug. 27, 1992). Once review of that document was completed, EPA staff prepared an "Assessment of Scientific and Technical Information" (the "Ozone Staff Paper") that synthesized the Criteria Document's technical information and made recommendations to the Administrator. *See* OJA 1790-2293. The Ozone Staff Paper recognized that most ozone health effects are transient and reversible, and that there is "only limited, suggestive evidence" that "[a]n increase in daily mortality [is] associated with O_3 exposure." *Id.* at 1870. Specifically, while "[s]everal efforts have been made to find associations between long-term O_3 exposure and chronic respiratory dysfunction and disease," these "associations between O_3 exposure and chronic health impacts have not been sufficiently demonstrated in humans." *Id.* at 1871; *see also id.* at 1870. The Staff Paper suggested adoption of a revised ozone NAAQS between a 0.07 and a 0.09 ppm daily maximum eight-hour ozone level, based on three-year averages of somewhere between the second- to the fifth-highest annual ozone concentration. *See id.* at 1974-77. (As the Staff explained, a 0.09 ppm level averaged over eight hours is roughly equivalent to the current 0.12 ppm level averaged over one hour. *See* 62 Fed. Reg. at 38,856, 38,858.) In so doing, the Paper predicted that the Administrator's selection among these broad options would require a "policy judgment," since exposure to ozone presents "a continuum of risk," as opposed to a threshold below which adverse health effects cease to occur. OJA 1971-72, 1976.

CASAC reviewed both the Criteria Document and the Staff Paper. CASAC agreed that, because "ozone may elicit a continuum of biological responses down to background concentrations," "the paradigm of selecting a standard at the lowest-observeable-effect level and then providing an 'adequate margin of safety' is no longer possible." OJA 237. Moreover, this "continuum" is such that "there is no 'bright line' which distinguishes any of the proposed standards (either

the level or the number of allowable exceedances) as being significantly more protective of health." *Id.* at 238. "For example, the differences in the percent of outdoor children . . . responding between the present standard and the most stringent proposal . . . are small and their ranges overlap for all health endpoints." *Id.* CASAC accordingly was reluctant to recommend any specific standard to the Administrator. *See id.* Acknowledging that the issue is not scientific, several CASAC members went on to express what they termed "'personal' preferences," with four favoring a standard of at least 0.09 ppm, three favoring 0.08 ppm, and one favoring a range of 0.08-0.09 ppm. *See id.*

In announcing the final standard, the Administrator stated both that "it is likely that O_3 may elicit a continuum of biological responses down to background concentrations" and that "a zero-risk standard is neither possible nor required by the Act." 62 Fed. Reg. at 38,863. She agreed that "there is no break point or bright line that differentiates between acceptable and unacceptable risks," but chose a 0.08 ppm standard over a 0.09 ppm standard because "[t]he general population as well as children and asthmatics would breathe cleaner air as a direct result of . . . the proposed standard." *Id.* at 38,864, 38,868. The Administrator "recognize[d]," however, that there was merit to "the views of those who argue that similarly large improvements in public health protection would result from a standard set at 0.07 ppm as compared to the proposed standard, such that, based on the same reasoning, the evidence warrants a standard set at 0.07 ppm." *Id.*

The Administrator offered three reasons for not going that far. *First*, no CASAC member had expressed a "'personal' preference" for a 0.07 ppm standard. *See* 62 Fed. Reg. at 38,868. *Second*, "[t]he most certain O_3-related effects . . . are transient and reversible (particularly at O_3 exposures below 0.08 ppm), and the more serious effects . . . are less certain." *Id.* *Third*, the Agency noted that "a 0.07 ppm level would be

closer to peak background levels." *Id.* In her Response to Comments document, the Administrator stated that peak background levels vary from region to region, and are generally in the range of 0.03 to 0.05 ppm. *See* OJA 173-77.

Rulemaking commenters argued that selection of any NAAQS level would be arbitrary without consideration of the costs of achieving compliance. The Administrator rejected this point, saying that the Agency and the D.C. Circuit had previously "interpreted section 109 of the Act as precluding consideration of the economic costs or technical feasibility of implementing NAAQS in setting them." 62 Fed. Reg. at 38,878. As for constraints on her discretion, the Administrator asserted that she was free to select any standard within the proposed range, and that her decision was "largely judgmental in nature" and need follow "no generalized paradigm"; nor need she even decide "what risk is 'acceptable'" through quantification "or any other metric." *Id.* at 38,883. As for whether she needed to follow a consistent standard-setting approach or provide a definite meaning to key statutory terms, the Administrator said that she "is not limited to any single approach to determining the margin of safety and may, in her judgment, choose a two-step approach, or perhaps some other approach, depending on the particular circumstances confronting her in a given NAAQS review." *Id.*

One thing the Administrator did not (and could not) say was that compliance costs and similar data were unavailable to illuminate the consequences of her decision. EPA endeavored in this case, as it had over the years, to keep cost data and other types of countervailing evidence—specifically, all evidence other than medical data showing adverse health consequences of pollution—out of the criteria development and CASAC review process. For instance, EPA refused to permit CASAC to review scientific literature showing that ground-level ozone, like stratospheric ozone, has beneficial effects in shielding the public from harmful ultra-violet radiation. *See, e.g.*, OJA 255-

71, 2666, 2676, 2759, 2849, 3089. The United States Department of Energy ("DOE"), attempting to impress the significance of these studies on CASAC, testified that revising the ozone NAAQS in the range proposed by the EPA Staff Paper would produce an estimated 2,000-11,000 additional cases of skin cancer per year, 130-260 additional cases of melanoma (including 25-30 deaths per year), plus 28,000 additional cataract cases annually. *Id.* at 255-71. DOE stressed that these detrimental health effects are "at least as well established as the relationship between ozone concentrations and lung disease." *Id.* at 257. A study by Office of Management and Budget staff members similarly concluded that the "adverse health effects of . . . EPA's more stringent NAAQS may be similar in magnitude to the respiratory-related beneficial effects of such an O_3 reduction." *Id.* at 2759, 2764; *see also id.* at 3089. CASAC members expressed interest in this issue, and EPA conceded that DOE's concern "could be big." *Id.* at 267. Nevertheless, EPA concluded that these data were legally beyond the bounds of consideration. *See id.* at 210.

Similarly, CASAC was forbidden by the Administrator from considering the data on compliance costs assembled in response to Executive Order 12,866 (President Clinton). Those data, prepared by EPA's economic consultants, estimated that the costs of bringing all areas of the country into compliance with the revised ozone NAAQS by 2010 would be $9.6 billion per year. By comparison, EPA predicted that the benefits would range from $1.5 billion to $8.5 billion annually. Regulatory Impact Analyses for the Particulate Matter and Ozone National Ambient Air Quality Standards and Proposed Regional Haze Rule (July 16, 1997) ("RIA") at ES-11, ES-17. The RIA estimated that an interim step—"partial attainment"—would cost $1.1 billion annually, with benefits in the range of $0.4 to $2.1 billion per year. *Id.* at ES-12, ES-17.

The difference between the high and low ends of EPA's benefits ranges is accounted for almost entirely by benefits that the RIA said could arise from preventing certain cases of "premature mortality." *See* RIA at ES-17 ("Mortality benefits represent about 90% of the high end benefit estimates."). But the CASAC-reviewed Staff Paper found no persuasive evidence of any such mortality effects. *See supra*, at 6. To resolve this inconsistency, the RIA cited subsequent studies, not analyzed in the Staff Paper or reviewed by CASAC, which were said to "document a possible relationship between ozone and premature mortality." RIA at 12-15. In the parallel PM rulemaking, however, EPA stated it could *not* rely on such unreviewed studies, "based on its long-standing practice of basing NAAQS decisions on studies and related information included in the pertinent air quality criteria and available for CASAC review." 62 Fed. Reg. at 38,862. In any event, EPA ultimately acknowledged "substantial uncertainty" on this point. *Id.* Once these mortality-reduction benefits and certain PM-related benefits are excluded, *see* RIA 12-15, EPA's estimate of the costs of full compliance exceeds its benefits estimates six times over ($9.6 compared to $1.5 billion). *See, e.g.*, ES-11, ES-17.

EPA's cost estimates changed substantially between the draft and final RIAs. EPA derived final cost estimates by assuming that all reasonably available control technologies with an annual cost per ton of emissions reductions of $10,000 or less would be used. *See* RIA at 7-7. The Agency further determined that attainment of the revised ozone NAAQS would require a 2,529 ton reduction in daily NOx emissions, and a 3,455 ton reduction in daily VOC emissions. *See id.* at 7-10. The Agency next estimated that the nation could achieve 22-24 percent of this NOx reduction target and 37-43 percent of the EPA VOC reduction target with technologies that satisfy the $10,000 cost cap, and deemed these reductions "partial attainment." *See id.* at 7-9. When the Agency then estimated the cost of full compliance, it again assumed that attainment

costs for the remainder of the required reductions (comprising the bulk of all required reductions) also would not exceed $10,000 per ton—even though all identifiable technologies costing less than that amount were already accounted for in the "partial attainment" figure. *See id.* at 9-5.

Because there is no empirical basis for EPA's $ 10,000 per ton cost cutoff, EPA conceded that it "has much less confidence in these cost estimates" than it does in its partial attainment estimates. RIA at ES-12. That caveat is seconded by a recent study asserting that EPA's full-attainment cost estimates assume an "implausibly high rate of technological progress." Randall Lutter, *Is EPA's Ozone Standard Feasible?*, Joint Center for Regulatory Studies at 7 (December 1999) (emphasis added); *see also* Darrell A. Winner & Glen R. Cass, *Effect of Emissions Control on the Long-Term Frequency Distribution of Regional Ozone Concentrations*, 34 Environ. Sci. & Technol. 2612, 2617 (June 15, 2000). While the effect of EPA's $10,000 cost cutoff was not apparent until the final RIA, the President's Council of Economic Advisors reached a comparable conclusion when it projected that EPA's ozone NAAQS would cost between $11.6 billion and $60 billion, compared to benefits of $200 million to $1 billion. *See* Memorandum from Alicia Munnell, CEA, to Art Frass, OMB, dated 12/13/96 ("CEA Memo") (cited in Stephen Huebner & Kenneth Chilton, *EPA's Case for New Ozone & Particulate Standards: Would Americans Get Their Money's Worth?*, Center for the Study of American Business Policy Study 27 (1997) ("*Huebner & Chilton*").

2. The PM Rulemaking

Unlike ozone, particulate matter is not a single substance. PM is instead the "generic term for a broad class of chemically and physically diverse substances that exist as discrete particles (liquid droplets or solids) over a wide range of sizes." 62 Fed. Reg. 38,652, 38,653 (July 18, 1997). These particles originate from both manmade and natural sources and may be either

emitted directly or formed in the atmosphere through transformations of gaseous emissions, including VOCs, NOx, and sulfur oxides ("SOx"). *Id.* The particles vary in size, a fact that EPA deems important both because particles' size "determines their behavior in the respiratory system," and because it determines their "atmospheric lifetime," which is "a key consideration in assessing health effects information because of its relationship to exposure." PMJA 1914 (PM Staff Paper). EPA has explained that "[t]he chemical and physical properties of PM vary greatly with time, region, meteorology, and source category, thus complicating the assessment of health and welfare effects." 62 Fed. Reg. at 38,653.

EPA has believed for years that, taken as a whole, PM is associated with respiratory and cardiovascular problems, including premature mortality. *See* 62 Fed. Reg. at 38,656. The initial PM NAAQS, issued in 1971, targeted airborne particles up to 45 micrometers in size, particles commonly referred to as total suspended particulate, or TSP. *See* 36 Fed. Reg. 8186 (Feb. 8, 1971); PMJA 1909 (Staff Paper). In 1987, EPA changed the "indicator" of PM from TSP to PM_{10}, which encompasses particles with a mean aerometric diameter less than or equal to 10 μm.

The rulemaking that produced the PM standards in this case occurred "under a highly-accelerated, court-ordered schedule," 62 Fed. Reg. at 38,654 & n.3 (citing *ALA v. Browner*, CIV-93-643 (D. Ariz. Oct. 6, 1994)), that had EPA struggling to complete both its PM Criteria Document and its PM Staff Paper. Echoing the Criteria Document, the PM Staff Paper stated that it is "important to emphasize the unusually large uncertainties associated with establishing standards for PM relative to other single component pollutants for which NAAQS have been set." PMJA 2153. The Staff Paper went on to explain that "[w]hile severe effects at the high concentrations of air pollution in the historical episodes are widely accepted as being causally related, there is less consensus as to the most

appropriate interpretation of studies finding associations of health effects with ambient levels of PM below the current NAAQS." *Id.* at 1993. Moreover, "[t]he majority of the evidence concerning health effects of PM exposure comes from epidemiological studies," which measure statistical correlation but not necessarily causation. *Id.* The Staff Paper found this point significant because "it has proven to be difficult to separate individual effects of multiple pollutants" in certain PM studies, raising the possibility that observed correlations might be due to "confounding" factors, not PM. *Id.* at 2002-03.

Further complicating matters, the Staff Paper explained that "available . . . information yields no demonstrated biological mechanism(s) that can explain the associations between ambient PM exposure and mortality and morbidity. . . . Thus, any discussion of possible mechanisms linking ambient PM exposures to mortality and morbidity effects is necessarily limited to hypotheses derived from animal or human studies conducted at exposure levels of PM constituents far higher than found in ambient air." PMJA 1952. The Staff Paper thus concluded that "there is an urgent need to expand ongoing research on the mechanisms by which PM . . . may cause adverse health effects." *Id.* at 1959.

The most serious of the health effects noted by the Staff Paper is a "small but significant increas[e] in mortality and morbidity in some sensitive populations at concentrations below the levels of the current ambient standards for PM." PMJA 2019. However, "it is reasonable to expect that some of the mortality associated with short-term pollution is occurring in the weakest individuals who might have died within days even without PM exposure." *Id.* at 1972. The Staff Paper thus cautioned that "it is not possible to confidently estimate quantitatively" the extent to which lives are actually shortened. *Id.* at 1974. Here again, the Paper recommended that "[m]ore research is needed." *Id.* at 2156.

The Staff Paper recommended establishing separate standards for fine and coarse PM. Fine PM consists of particles measuring between approximately 0 and 3 μm in diameter; coarse PM consist of particles between approximately 1 and 10 μm. PMJA 2127. The Paper acknowledged that "the epidemiological data providing a direct comparison of the health effects of fine and coarse particles are quite limited in comparison to that of PM_{10} (which contains both coarse and fine mode fractions)." *Id.* at 2020. It speculated nonetheless that fine particles "are a better surrogate for that fraction of ambient PM that is most clearly associated with the health effects observed in community air pollution studies at levels below the current standards." *Id.* at 2049. It also asserted that fine particles are potentially more dangerous to public health because they penetrate deeper into the respiratory system. *See, e.g., id.* at 1914.

As with ozone, the PM Staff Paper declined to recommend specific standards, saying instead that the ultimate choice of a PM standard is a "policy" decision. PMJA 2136. PM presents a "continuum of exposures," such that "attempting to identify 'lowest observed effects levels' and adding margins of safety below such levels is not an appropriate approach in this case." *Id.* at 2134-35. Moreover, "[r]elative to other single pollutants for which NAAQS have been set, establishing appropriate ranges of levels for $PM_{2.5}$ [fine PM] standards involves unusually large uncertainties." *Id.* at 2135. In considering this "continuum," the PM Staff Paper (like the Ozone Staff Paper) did not take into account any offsetting health or non-health factors. *See id.* at 2134-25.

After reviewing the Criteria Document and Staff Report, CASAC recommended that EPA retain the current PM_{10} NAAQS and establish a $PM_{2.5}$ NAAQS. PMJA 3162. But it reached "no consensus on the level, averaging time, or form of a $PM_{2.5}$ NAAQS." *Id.* CASAC instead provided the Agency with a table setting forth the disparate views of its members.

CASAC's cover letter stated that the table "appears to defy further characterization," but "[p]art of this diversity of opinion can be attributed to the accelerated review schedule" ordered by the Arizona district court. *Id.* at 3163. CASAC, like EPA's Staff Paper, stressed that "[t]he Agency must immediately implement a targeted research program to address . . . unanswered questions and uncertainties," in order "to avoid being in a similar situation when the next PM NAAQS review cycle is under way." *Id.* at 3163-64; *see also id.* at 3142-43.

According to the table transmitted by CASAC, only two of the 21 panelists endorsed an annual $PM_{2.5}$ standard as low as the 15 $\mu g/m^3$ standard ultimately adopted by EPA, while eight of the 21 opposed establishing an annual $PM_{2.5}$ standard at all. PMJA 3165. The majority of members opposing the low $PM_{2.5}$ standard chosen by EPA "were influenced, to varying degrees, by the many unanswered questions and uncertainties regarding the issue of causality." *Id.* at 3163. CASAC was especially critical of epidemiological studies, since that evidence "is not unambiguous" given that "[t]he risk factors being reported are not large and they have relatively large uncertainties." *Id.* at 3140. CASAC also emphasized that "[i]t is of paramount importance to know whether some, most, or all of the deaths are advanced by only one or several days." *Id.* at 3141.

EPA's final rule acknowledged the great "uncertainty in the characterization of health effects attributable to exposure to ambient PM." 62 Fed. Reg. at 38,655. Based primarily on epidemiological studies, however, the Administrator determined that the existing PM NAAQS was insufficient from a public health standpoint. *See, e.g., id.* at 38,655. The Administrator agreed that there is no known causal mechanism whereby PM levels below the existing NAAQS could harm public health. *See id.* at 38,656. She also acknowledged that the health effects at issue might be caused by only certain types of particles, not PM generally. *See id.* at 38,667. Despite these "significant uncertainties," she determined that there is an

"adequate basis for regulatory decision making at this time." *Id.* at 38,655.

The Administrator recognized in selecting a fine PM standard that, as with ozone, she faced both uncertainties and "a continuum of effects associated with exposures to varying levels of PM." 62 Fed. Reg. at 38,673. In response to comments that the selection of any level along that continuum would be arbitrary unless balanced against countervailing considerations, the Administrator again asserted her prerogative to promulgate revised NAAQS using *ad hoc* analysis that recognizes "no generalized paradigm," that "may not be amenable to quantification in terms of what risk is 'acceptable' or any other metric," and that is "largely judgmental in nature." *Id.* at 38,688.

The Administrator's most basic choice was her decision to regulate PM based on particle size rather than chemical composition. She explained that "the available evidence is not sufficient to *exclude* nitrates or any other class of fine particles." 62 Fed. Reg. at 38,667 & n.26 (emphasis added). In contrast, she set different standards for small ("fine") and large ("coarse") particles, despite agreeing that the evidence on this point was also not entirely satisfactory, as relatively few studies have addressed fine PM, as opposed to PM generally. *See id.* at 38,665; *see also Huebner & Chilton* at 11-12 (only 7 of the 27 studies identified in Staff Paper actually address $PM_{2.5}$); Draft Memorandum from Rosina Bierbaum, OSTP, to Sally Katzen, OIRA (President's Office of Science and Technology Policy determines that "[t]he database for actual levels of $PM_{2.5}$ is . . . very poor;" "only a handful of studies have actually studied $PM_{2.5}$ per se," and "current data do not support clear associations of PM effects with . . . fine particles") (as quoted in Dana C. Joel, *Surprising Critics of the New Clean Air Standards: The U.S. Government*, Citizens for a Sound Economy Foundation Issue Analysis (Apr. 9, 1997) ("*Surprising Critics of the New Clean Air Standards*"). The

selection of $PM_{2.5}$ as the fine PM indicator was thus made "largely [as] a policy judgment." 62 Fed. Reg. at 38,665.

The Administrator's selection of a coarse particle indicator was also a subject of considerable discussion. Here, the Administrator retained the current PM_{10} measure, rather than accepting the "views of several CASAC panel members" who "suggested" replacing it with a $PM_{10-2.5}$ indicator—an indicator that measures only coarse particles and excludes fine ones. 62 Fed. Reg. at 38,668. She defended that selection by asserting that "the only studies of clear quantitative relevance to effects most likely associated with *coarse* fraction particles have used *undifferentiated* PM_{10}," and making the pragmatic observation that a "large" "monitoring network" is "already in place for PM_{10}." *Id.* (emphasis added).

Having chosen to regulate both fine and coarse PM and set the indicators for both, the Administrator proceeded to set actual standards. She determined that she would not adjust the levels of the current annual and 24-hour PM_{10} standards "[g]iven the uncertainties in the available scientific evidence." 62 Fed. Reg. at 38,678. As for fine PM, she decided to promulgate an annual standard to control emissions generally, and a supplementary 24-hour standard to protect against high peak concentrations and seasonal emissions, explaining that this would be the most "efficient approach." *See id.* at 38,570.

Whereas "uncertainties" in the "scientific evidence," 62 Fed. Reg. at 38,678, had prompted her to leave in place the current PM_{10} standards, the Administrator decided with respect to an annual fine PM standard that she would regulate, "*despite* well recognized uncertainties," down to levels "somewhat *below* where the body of epidemiological evidence is *most* consistent and coherent." *Id.* at 38,675 (emphasis added). In her view, "the strength of the evidence of effects increases for concentrations that are at or above the long term (*e.g.*, annual) mean levels reported for [certain] studies." *Id.* at 38,676. Studies reported in the Criteria Document had found mean

concentrations to "range from about 11 $\mu g/m^3$ to 30 $\mu g/m^3$." *Id.* After reciting these results, the Administrator concluded that "[t]aken together, and placing greatest weight on those studies that were clearly statistically significant, this evidence suggests that an annual standard level of 15 $\mu g/m^3$ is appropriate." *Id.* The Administrator did not dispute that this level is "*below* the range of annual data *most strongly* associated with both short- and long-term exposure effects." *Id.* (emphasis added). Nor did she rely on peak background levels or transiency and irreversibility of health effects, as she had in choosing an ozone NAAQS. *See id.*

The Administrator then concluded that, having enacted such a strict annual fine PM standard, there was "no need to consider levels in the lower portion" of the range suggested for the 24-hour fine PM standard. 62 Fed. Reg. at 38,677. "Further," she said that "the risk associated with peak 24-hour exposures in otherwise clean areas is not well enough understood at this time to provide a basis for selecting the more restrictive levels in the range of 50 to 65 $\mu g/m^3$." *Id.* Based on these rationales, she chose a 65 $\mu g/m^3$ level. *See id.* She did not discuss either the levels at which the evidence is "most strongly associated" with exposure effects, nor the mean concentrations from studies, as she had in choosing an annual $PM_{2.5}$ NAAQS. *See id.*

As with the ozone NAAQS, the Administrator also did not consider predicted compliance costs or any other non-medical information bearing on the consequences of her action. *See* 62 Fed. Reg. at 38,683; PMJA 312, 319 (EPA's Response to Comments). EPA acknowledged, however, that full attainment with its revised PM NAAQS by 2010 would cost at least $37 billion annually, making this standard the most expensive environmental program ever. Even "partial attainment," as defined by EPA, would cost $8.6 billion. *See* RIA at ES-12, 13. In contrast, the Agency estimated the benefits of full attainment to range from $20 to $110 billion, and those of

partial attainment to range from $19 to $104 billion. *See id.* at 12-1.

As with ozone, the difference between the high and low-end benefits estimates consists primarily in how mortality benefits are estimated and valued. *See, e.g.*, RIA at 12-44. The RIA calculated the high end estimates by valuing every avoided premature mortality at $4.8 million. *See id.* at 12-15, 16, 41. The RIA made an alternative estimate, however, in response to criticisms that estimating benefits from PM reductions should be based on "not only how many premature deaths are avoided, but . . . how long these deaths are postponed." *Id.* at 12-16. That alternative, reflected in EPA's low-end estimates, assigned a set value to every "statistical life-year extended." On that assumption, the fine PM standards' predicted benefits are significantly less than their predicted costs. *See id.*

The PM cost calculations are also similar to the ozone calculations in that they impose a $10,000 cost cap for "partial attainment," then assume that full attainment can be reached with measures that do not exceed this cap. *See* RIA at 6-16, 9-7. The President's Council of Economic Advisors determined that EPA's analysis "understates the true costs . . . by orders of magnitude." CEA Memorandum (as quoted in *Surprising Critics of the New Clean Air Standards* at 1).

C. The Congressional Response

Congress responded to EPA's final rules by postponing implementation of the revised ozone and PM standards, thus providing time for pre-implementation judicial review. *See* Pub. L. No. 105-178, §§ 6101-03, 112 Stat. 465 (1998). Specifically, Congress codified an Executive Order, issued the same day as the final ozone and PM rules, that delayed the implementation of the PM NAAQS until at least 2005. *See id.* § 6102; 62 Fed. Reg. 38,421, 38,427-28 (July 18, 1997). Congress also pushed back implementation of the ozone NAAQS by one year. *See* Pub. L. No. 105-178, § 6103(a).

And Congress emphasized that "[n]othing" in its action "shall be construed . . . to be a ratification of the ozone or [PM] standards." *Id.* § 6104.

D. The Court of Appeals Proceedings

1. Panel Proceedings

Before the D.C. Circuit, EPA continued to assert that it is barred from considering non-health factors including compliance costs in setting NAAQS, and that it is even barred from considering the protective health effects of ground-level ozone. *See, e.g.*, EPA Ozone Br. at 43. Based on *Lead Industries*, the D.C. Circuit agreed with the Agency's refusal to consider compliance costs. "Our cases read § 109(b)(1) as barring EPA from considering any factor other than 'health effects relating to pollutants in the air.'" Pet. App. 15a (citing, *inter alia*, *Lead Industries*, 647 F.2d at 1148). The D.C. Circuit emphasized that its "*Lead Industries* decision was made in *Chevron* step one terms," and held that *Lead Industries* unambiguously "precludes" EPA from considering costs. *See id.* at 19a.

The D.C. Circuit disagreed, however, with EPA's claim that "nothing in the statute requires [the Administrator] to make *any* specific 'findings' or to structure her decisionmaking in *any* particular way." EPA Ozone Br. at 43 (emphasis added). Instead, the court held that section 109 must be construed to provide some "intelligible principle" that guides the exercise of agency discretion. *See* Pet. App. 5a. The court found that EPA's construction of the Act fails this test by not "speak[ing] to the issue of degree." *Id.* at 7a. It then illustrated the point by using the Agency's justification for choosing a 0.08 ppm level for ozone. *See id.* at 8a-11a. The court explained that, while EPA claims to have chosen 0.08 ppm over 0.09 ppm "because more people are exposed to more serious effects at 0.09 than at 0.08," it "never contradict[ed] the intuitive proposition, confirmed by data in its Staff Paper, that reducing the [0.08]

standard to [0.07] would bring about comparable changes." *Id.* at 8a. EPA responded that "a 0.07 standard would be 'closer to peak background levels,'" but "a 0.08 level, of course, is also *closer* to these peak levels than 0.09." *Id.* at 9a (emphasis in original).

The court discounted the Administrator's reliance on individual CASAC members on the ground that they merely stated their "personal" preferences—preferences that provided no reasoned basis for preferring a 0.08 ppm or 0.09 ppm level to a 0.07 ppm level. *See* Pet. App. 8a. As the court put it:

> EPA's explanations for its decisions amount to assertions that a less stringent standard would allow the relevant pollutant to inflict a greater quantum of harm on public health, and that a more stringent standard would result in less harm. Such arguments only support the intuitive proposition that more pollution will not benefit public health, not that keeping pollution at or below any particular level is "requisite" or not requisite to "protect the public health" with an "adequate margin of safety . . . ."

Id. at 7a.

The court found the same flaws in EPA's attempts to justify its PM NAAQS. EPA defended those standards "on the basis that there is greater uncertainty that health effects exist at lower levels than the level of the standard." Pet. App. 10a. But the court responded that "the increasing-uncertainty argument is helpful only if some principle reveals how much uncertainty is too much. None does." *Id.* The court accordingly "remand[ed] the cases for EPA to develop a construction of the act that satisfies" the nondelegation doctrine and, "if appropriate, modify the disputed NAAQS in accordance with that construction." *Id.* at 4a-5a.

The D.C. Circuit emphasized that, although some form of cost-benefit or similar analysis could ordinarily serve as the

necessary "intelligible principle," such an approach "is not available" because of *Lead Industries*. Pet. App. 15a (internal quotation omitted). The court suggested one alternative construction for the Agency to consider, a principled "criterion of probability" analysis based on a "generic unit of harm that takes into account population affected, severity and probability." *Id.* at 16a. The court acknowledged, however, that since "EPA may not consider cost," it may have to "conclud[e] that there is no principle available" that would be constitutionally sufficient. *Id.* at 18a. Judge Tatel dissented from the court's nondelegation analysis. *See id.* at 59a.

In contrast, the court unanimously reversed EPA's refusal to consider the potential health protective effects of ground-level ozone, labeling "bizarre" the Agency's contention "that a statute intended to improve human health would . . . lock the agency into looking at only one half of a substance's health effects in determining the maximum level for that substance." Pet. App. 47a. As for particulate matter, the court also unanimously reversed the Agency's use of PM_{10} as an indicator for coarse PM. The court explained that, having determined that coarse and fine particles should be regulated separately, EPA acted arbitrarily and capriciously by using an indicator for coarse particles that includes fine particles. *See id.* at 49a-53a. The court further noted that EPA's reliance on a "pragmatic" basis for this decision—specifically, the fact that a monitoring program for PM_{10} already exists—is contrary to EPA's own position that it may not consider pragmatic factors in setting NAAQS. *See id.* at 52a-53a.

Finally, the court of appeals addressed Subpart 2 of the Act, which establishes a specific schedule for reducing ozone levels nationwide. *See supra*, at 4, 5. The court accepted EPA's contention that, notwithstanding the detailed provisions of Subpart 2, the Agency may still revise the ozone NAAQS. *See* Pet. App. 31a-43a. In doing so, however, the court unanimously rejected EPA's contention that "Subpart 2

specifically provides classifications and attainment dates only for nonattainment designations under the [existing] ozone NAAQS." *Id.* at 37a. The text and drafting history of this provision confirm that it applies to all ozone NAAQS, including revised NAAQS. *See id.* at 38a-39a. Because Congress' handiwork was "purposeful and not the drafting error that EPA's interpretation implies," "EPA is precluded from enforcing a revised primary ozone NAAQS other than in accordance with the classifications, attainment dates, and control measures set out in Subpart 2." *Id.* at 34a, 39a.

2. Rehearing Proceedings

In response to EPA's rehearing petition, the panel underscored that, because EPA's statutory interpretation lacked an "intelligible principle," remand to the agency was the appropriate remedy: "[J]ust as we must defer to an agency's reasonable interpretation of an ambiguous statutory term, we must defer to an agency's reasonable interpretation of a statute containing only an ambiguous principle by which to guide its exercise of delegated authority." Pet. App. 76a (citing *Chevron U.S.A. Inc. v. NRDC*, 467 U.S. 837, 866 (1984)). The panel also dismissed EPA's continuing contention that it should not be required to consider its standards' detrimental health effects, noting that the Agency's further arguments do not "warrant consideration in a published opinion." *Id.* at 82a.

The panel also unanimously rejected EPA's new argument that it lacked jurisdiction to reach the Subpart 2 issue because the Agency "has taken no final action implementing the revised NAAQS." Pet. App. 77a, 79a. The court explained that EPA's promulgation of the revised NAAQS "triggered" certain statutory provisions that "impose a number of requirements upon the states." *Id.* at 78a.

The panel also rejected EPA's reiterated contention that Subpart 2 amounts to a scrivener's error. *See* Pet. App. 79a. The panel noted that "all five Subparts of the Clean Air Act

providing requirements for nonattainment areas" contain the same language. *Id.* The panel then clarified that its holding merely meant that a revised ozone NAAQS "can be enforced only in conformity with Subpart 2," not necessarily that such a NAAQS "cannot be enforced" at all. *Id.* at 81a. Judge Tatel concurred, noting that this would "leav[e] open the possibility" that Subpart 2 applies only until an area attains the existing ozone NAAQS, such that "in areas that have attained the ozone standard, nothing precludes enforcement of the new standard" outside of the Subpart 2 framework. *Id.* at 88a, 89a. The *en banc* court unanimously denied rehearing on this issue.

Two opinions dissenting from the denial of rehearing *en banc* addressed the main statutory interpretation questions. *See* Pet. App. 92a. Judge Silberman's dissent disagreed with the panel majority's use of the nondelegation doctrine, but emphasized that he was "quite uncertain" whether EPA's analysis satisfied the demands of the "arbitrary and capricious standard." *Id.* at 95a-96a. Judge Tatel, joined by Chief Judge Edwards and Judge Garland, also dissented from denial of rehearing because he disagreed with the panel's use of the non-delegation canon. *See id.* at 97a.

E. The Grant of the Petition and Cross-Petition

The Government petitioned for *certiorari* on the nondelegation and Subpart 2 issues, and ATA cross-petitioned to challenge the court of appeals' holding that EPA must "ignore all factors 'other than health effects relating to pollutants in the air'" in setting NAAQS. Cross-Pet. (i). ATA argued that the cross-petition should be granted because reversing the D.C. Circuit on this point would permit the Court to "avoid[] the constitutional nondelegation issue on which EPA focuses." *Id.* at 1. This Court granted both petitions, and set a briefing schedule. *See* 120 S. Ct. 2193 (2000); 120 S. Ct. 2003 (2000).

SUMMARY OF THE ARGUMENT

The court of appeals recognized the trilemma logically entailed by the *Lead Industries* interpretation: *either* (1) the Act must direct EPA to set a zero-level NAAQS for non-threshold pollutants like ozone and PM; *or* (2) EPA must be empowered to select arbitrarily some level above zero for these pollutants (the selection necessarily being arbitrary because any forthright consideration of medical factors alone would likely produce zero standards); *or else* (3) *Lead Industries* must have been wrongly decided.

What the D.C. Circuit did not say expressly was that it is entirely unreasonable to assume Congress would have delegated the authority presupposed by options (1) and (2). If Congress ever intended the "zero risk" standards of option (1)—which, the court of appeals noted, would require "de-industrialization" or worse, Pet. App. 15a n.4—then surely Congress, and not EPA, would be required to make that policy choice explicitly. *See Industrial Union Dep't v. American Petroleum Inst.*, 448 U.S. 607, 646, 675 (1980) (opinions of the plurality and Rehnquist J., concurring) ("*Benzene*"). Likewise, the second option, arbitrary selection of some level above zero, runs afoul of this Court's decisions requiring agencies "to apply *some* limiting standard" in the exercise of delegated authority. *See AT&T Corp. v. Iowa Utils. Bd.*, 525 U.S. 366, 386-90 (1999) (emphasis in original). Finally, options (1) and (2) alike presuppose that Congress might delegate to EPA, the courts, or both, extraordinary authority and discretion over decisions of great "economic and political significance"—a further presumption that cannot be squared with this Court's precedents. *See, e.g., FDA v. Brown & Williamson Tobacco Corp.*, 120 S. Ct. 1291, 1315 (2000) ("[W]e are confident that Congress could not have intended to delegate a decision of such economic and political significance . . . in so cryptic a fashion."). *See* Part I, *infra*.

Logically, then, the third option—that *Lead Industries* was wrongly decided—must be the case and, in fact, *is* the case under any straightforward interpretation of the Act. *First*, primary NAAQS are set at levels "requisite to protect the public health" "with an adequate margin of safety." Because "public health" is left undefined, that term must be given its "ordinary" and "natural" meaning. By 1970, when section 109(b) was enacted, public health had already taken the meaning given it by public health professionals whose job is to improve health through a synthesis of the medical and social sciences, including economics. Tellingly, the critical role that costs play within this public health tradition is directly at odds with *Lead Industries'* absolute bar on considering such factors in setting NAAQS. *See* Part II.A, *infra*.

Second, provisions surrounding section 109(b) give further testimony to the important role countervailing factors should play in NAAQS rulemakings. Specifically, the information on which NAAQS are to be "based" is not limited to the section 108(a)(2) Criteria Document (which itself should properly include non-medical information), but also includes CASAC's findings, recommendations, and comments, as well as comments and data from the public. Section 108(b) accordingly requires EPA to develop data on control costs *simultaneously* with preparation of the Criteria Document and well in time to be used in the relevant NAAQS rulemaking. Likewise, section 109(d) requires, *inter alia*, that CASAC "advise the Administrator of any adverse public health, welfare, *social, economic or energy effects* which may result from" EPA's proposed NAAQS. *See* Part II.B, *infra*. *Finally*, as the record here demonstrates, EPA simply cannot achieve the Act's statutorily-codified purpose of "public health" protection—or even avoid doing more harm than good—without taking countervailing factors into account. *See* Part II.C, *infra*.

One last option requires exploration. Perhaps, notwithstanding *Lead Industries*, EPA often does consider

countervailing factors such as compliance costs in setting NAAQS—albeit covertly and beyond public view. In fact, the scholarly literature establishes that economic analyses played significant, behind-the-scenes roles in setting both the 1979 ozone NAAQS and the 1987 PM NAAQS. The Administrator's repeated invocations of her wide, discretionary powers of "judgment" therefore might be meant as hints that such analyses played similar roles here. Such disguised decisionmaking would underscore the conflict between EPA's professed interpretation of section 109 and its practice under analogous Clean Air Act provisions, where, notwithstanding *Lead Industries*, the Agency has openly and successfully claimed authority to consider economic factors. *See* Part III.A, *infra*. Even more important, however, such concealed decisionmaking would (1) undermine Presidential oversight under the cost-and-benefit-assessment provisions of Executive Order 12,866; (2) defeat similar requirements of the Unfunded Mandates Reform Act of 1995; and (3) subvert the foundational premises of judicial review on traditional rationality grounds. *See* Part III.B, *infra*. For all of the above reasons, *Lead Industries* should be rejected by the Court.

ARGUMENT

As noted in our *certiorari* briefing, the D.C. Circuit has treated *Lead Industries* as a precedential leper—diseased but untouchable—ever since it re-endorsed it in fashioning a consensus interpretation of another Clean Air Act provision in *NRDC v. EPA*, 824 F.2d 1146, 1154-58 (D.C. Cir. 1987) (*en banc*) ("*Vinyl Chloride*"). *Lead Industries* itself directly addressed and rejected only arguments that an "economic and technological feasibility" test must be used in establishing "margins of safety" under section 109, and that the Agency must show "clear" health effects before regulating. *Lead Indus. Ass'n v. EPA*, 647 F.2d 1130, 1148, 1153-54 (D.C. Cir. 1980). But the D.C. Circuit has since read *Lead Industries* to preclude consideration of *all* factors of "cost," *American Petroleum Inst.*

v. Costle, 665 F.2d 1176, 1185 (D.C. Cir. 1981), and even indirect *health* effects such as "health risks from unemployment" caused by a more stringent NAAQS. *NRDC v. EPA*, 902 F.2d 962, 973 (D.C. Cir. 1990), *vacated in part*, 921 F.2d 326 (D.C. Cir.), *cert. dismissed sub nom. Alabama Power Co. v. NRDC*, 498 U.S. 1075 (1991). This line of cases has become so extreme that the panel below brushed aside without comment arguments that the Agency erred by ignoring *health* effects resulting from disruption of the States' ongoing air-quality improvement efforts. *See* OJA 223; PMJA 319. "*Lead Industries*," as used below and elsewhere, has thus become a shorthand for the D.C. Circuit's extreme insistence that all countervailing factors (excepting only a pollutant's direct health benefits) are "non-health" factors and therefore barred from EPA's consideration in setting NAAQS.

I. THIS COURT'S DECISIONS NEGATE THE PREMISES ON WHICH *LEAD INDUSTRIES* IS PREDICATED.

No statute, and certainly not the Clean Air Act provisions at issue here, can be interpreted in a contextual vacuum. To be sure, "[t]he task of resolving the dispute over the meaning of" statutes must begin "with the language of the statute itself." *United States v. Ron Pair Enters., Inc.*, 489 U.S. 235, 241 (1989). But "as [this Court] ha[s] repeatedly stated, the meaning of statutory language, plain or not, depends on context." *Holloway v. United States*, 526 U.S. 1, 7 (1999) (internal quotation and citations omitted); *see also, e.g., Schenck v. Pro-Choice Network*, 519 U.S. 357, 395 (1997) (opinion of Breyer, J.) ("Words take on meaning from context."). The requirements for NAAQS standard-setting, therefore, must be decided within "the broader context of [the statute]," including the nature of the problem Congress sought to solve. *Robinson v. Shell Oil Co.*, 519 U.S. 337, 345 (1997).

The court of appeals set out the context here in detail. To begin with, "EPA regards ozone definitely, and PM likely, as

nonthreshold pollutants, *i.e.*, ones that have some possibility of some adverse health impact (however slight) at any exposure level above zero." Pet. App. 5a. Accordingly, "the only concentration for ozone and PM that is utterly risk-free, in the sense of direct health impacts, is zero." *Id.* at 6a. EPA thus recognizes "that a less stringent standard would allow the relevant pollutant to inflict a greater quantum of harm on public health, and that a more stringent standard would result in less harm." *Id.* at 7a. But that truism does not mean "that keeping pollution at or below any particular level is 'requisite' or not requisite to 'protect the public health' with an 'adequate margin of safety.'" *Id.*

Logically, this context forces EPA to pursue just one of three regulatory options. *First*, "EPA could make its criterion the eradication of any hint of direct health risk"—an approach that "would require the agency to set the permissible levels of both pollutants here at zero." Pet. App. 15a. "A zero-risk policy might seem to imply de-industrialization, but in fact even that seems inadequate to the task (and even if the calculus is confined to direct risks from pollutants, as opposed to risks from the concomitant poverty)." *Id.* at 15a n.4. As EPA's Staff Paper and a World Bank report show, "PM (at least) results from almost all combustion, so only total prohibition of fire or universal application of some heretofore unknown control technology would reduce manmade emissions to zero." *Id.*

Second, EPA could select a non-zero standard without considering the factors that might counsel in favor of or against a more or less stringent NAAQS. But the difficulty with this option is that any such selection must, of necessity, be made arbitrarily. In these very rulemakings, "the agency rightly recognizes that the question is one of degree," but nonetheless "offers no intelligible principle by which to identify a stopping point." Pet. App. 11a. Indeed, EPA all but admits to having made arbitrary choices by repeatedly asserting that it was free to follow an *ad hoc* standard-setting approach that recognizes

"no generalized paradigm," that "may not be amenable to quantification in terms of what risk is 'acceptable' or any other metric," and that is "largely judgmental in nature." 62 Fed. Reg. at 38,864, 38,683, 38,688.

Finally, "cost-benefit analysis, mentioned in [*International Union, United Automobile, Aerospace & Agricultural Implement Workers of America, UAW v. OSHA*, 938 F.2d 1310, 1319-21 (D.C. Cir. 1991) ("*Lockout/Tagout I*")]," would provide a third alternative for NAAQS standard-setting but for the fact that it is precluded by *Lead Industries*. Pet. App. 14a-15a. The court of appeals' citation makes clear that, as used below, "cost-benefit analysis" means "only a systematic weighing of the pros and cons." *Lockout/Tagout I*, 938 F.2d at 1321; *accord* Stephen G. Breyer, *et al.*, *Administrative Law & Regulatory Policy* 181 (4th ed. 1999) ("cost-benefit criteria would be understood in a less technical and more commonsensical way, as an invitation to balancing a range of variables"). This concept is broad enough to include properly performed analyses under "significant risk" and similar rubrics. *Cf. Benzene*, 448 U.S. at 641-42 (plurality opinion). Indeed, the court below suggested that EPA might develop an intelligible principle based on one such approach —"a generic unit of harm," reflecting "Quality-Adjusted Life Years." *Id.* at 16a-18a. But the court recognized that even that approach might well be precluded by *Lead Industries*. *See id.* at 18a.

Only the third of these options—a systematic weighing of pros and cons based upon rejection of *Lead Industries* —can be squared with this Court's precedents. As an initial matter, the option of a zero-risk policy is expressly disclaimed by even EPA, *see* Pet. App. 15a; *supra* at 7, and, in any event, could not be adopted without the clearest possible evidence of congressional intent. As this Court has noted, it is generally "unreasonable to assume that Congress intended to give [an agency] the unprecedented power over American industry" to "impose enormous costs that might produce little, if any,

benefit." *Benzene*, 448 U.S. at 645 (plurality opinion); *see also id.* at 675-76 (opinion of Rehnquist, J.). Needless to say, there is no such evidence of intent here.

The second option, non-zero standards set by decisionmakers blinded to all countervailing factors, is similarly precluded by this Court's decisions. As *Iowa Utilities* holds, all congressional delegations "require" the agency "to apply *some* limiting standard, *rationally* related to the goals of the Act." *Iowa Utilities*, 525 U.S. at 388 (first emphasis in original). The need for such limiting principles is especially compelling where, as here, the entire economy is to be regulated. *See Fahey v. Mallone*, 332 U.S. 245, 250 (1947) (holding that delegations confering power over "unprecedented economic problems of varied industries" must be more precise than those regarding "a single type of enterprise"); *Clinton v. New York*, 524 U.S. 417, 487 (1998) (Breyer J, concurring). Because selection of *any* non-zero NAAQS cannot be made "rationally" without a weighing of pros and cons, *see Iowa Utilities*, 525 U.S. at 388, any non-zero NAAQS established under *Lead Industries* will necessarily be arbitrary.

Both zero-risk and arbitrarily-set standards also suffer from a further flaw under this Court's decisions. *Lead Industries* must mean either (as the D.C. Circuit says) that Congress itself barred EPA from considering countervailing factors—an implausible proposition for the reasons summarized below, *see* Part II—or else that Congress delegated to EPA the discretion to ignore all "non-health" factors in setting NAAQS. This Court traditionally "hesitates," however, "before concluding that Congress has intended such an implicit delegation." *FDA v. Brown & Williamson Tobacco Corp.*, 120 S. Ct. 1291, 1296, 1314 (2000). Indeed, "[i]t is highly unlikely that Congress would leave" choices of such magnitude to an administrative agency. *MCI v. AT&T*, 512 U.S. 218, 231 (1994). Thus, "[t]he implausibility of Congress's leaving a highly significant issue unaddressed . . . is assuredly one of the factors to be considered

in determining whether there is ambiguity." *Christensen v. Harris County*, 120 S. Ct. 1655, 1664 n.1 (2000) (Scalia J., concurring); *accord id.* at 1667 (Breyer, J., dissenting) (*Chevron* deference inapplicable "where one has doubt that Congress actually intended to delegate interpretative authority to the agency.")

This Court's decisions alone are therefore enough to prove that *Lead Industries* was wrongly decided—unless, perhaps, the statutory text were so absolutely clear as to lead inescapably to the conclusion that Congress deliberately precluded EPA from considering all supposedly "non-health" factors in setting NAAQS. But just the opposite is the case. Far from compelling the *Lead Industries* reading, the statutory text of section 109(b)(1), the surrounding statutory provisions and the Act's public health purpose all show that Congress contemplated that EPA *would* weigh such factors in the standard-setting balance.

II. THE ACT'S TEXT, STRUCTURE AND PURPOSE SHOW THAT EPA MUST CONSIDER NON-HEALTH FACTORS IN SETTING NAAQS.

The D.C. Circuit has most authoritatively stated its rationale for *Lead Industries* as follows: "ambient air standards set under section 109(b) must be based on 'air quality criteria,' which section 108 defines as comprising several elements, all related to health," thereby excluding "non-health" factors. *Vinyl Chloride*, 824 F.2d at 1157-59. That rationale is demonstrably wrong. *First*, the key text of section 109(b) was added in 1970 to direct that EPA protect "public health," a term of art that traditionally signals the consideration of both medical and economic factors. *See* Part II.A, *infra*. *Second*, surrounding statutory provisions in sections 108(a), 108(b) and 109(d) all confirm that what the D.C. Circuit implies are "non-health" factors, including compliance costs, are to be considered in setting NAAQS. *See* Part II.B, *infra*. *Finally*, the Act's purposes, as stated in section 101(b), further reinforce the

role that these factors must play in standard-setting. *See* Part II.C, *infra*.

A. Section 109(b)(1)'s "Public Health" Focus Necessarily Entails Consideration of Non-Health Factors.

The Act's core standard-setting provision, section 109(b)(1), reads as follows:

> National primary ambient air quality standards . . . shall be ambient air quality standards the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health.

42 U.S.C. § 7409(b)(1). The aim of this provision is manifestly to protect "public health," but precisely what is meant by those two words (or other key terms like "adequate" or "requisite" or "margin of safety") is nowhere defined. We do know that section 109(b) was added by Congress in 1970 to replace a previous State/federal enforcement mechanism that provided that pollution that "endangers the health or welfare *of any persons* shall be subject to abatement." *See* Pub. L. No. 90-148 § 108(a) (emphasis added). It is therefore logical to presume that Congress intended to shift the focus away from pollution that endangers "any person" and toward a broader concept of "public health."

With no definition in the statute itself, "public health" must be construed "in accordance with its ordinary or natural meaning." *FDIC v. Meyer*, 510 U.S. 471, 476 (1994). "Public health" was, of course, a well-established profession in 1970. The discipline then, as now, is practiced through a synthesis of medical and social sciences, with a significant emphasis on economics. As the shift away from the language referring to the "health" of "any person" and toward the aggregate expression "public health" implies, the 1970 Congress must

have expected EPA to set standards by acting like public health professionals, engaged in the traditional practice of their combined medical and social science discipline.

The authoritative public health definition available to the 1970 Congress appeared in C.E.A. Winslow's THE COST OF SICKNESS AND THE PRICE OF HEALTH, published in 1951 as a study for the World Health Organization on the comparative costs and effectiveness of various measures for controlling tuberculosis. That study defines "public health" as follows:

> Public health is the science and the art of preventing disease, prolonging life, and promoting physical health and efficiency [by various means including] the development of social machinery which *will ensure* to every individual in the community *a standard of living* adequate to the maintenance of health.

Id. at 28 (emphasis added). As is evident from the title and contents of Winslow's seminal work, costs provide an important counter-balance in the practice of "public health," as Winslow understood the term. In particular, costs are integral in choosing the "social machinery" for providing specific forms and levels of health protection and in determining the effect which specific measures will have on the population's "standard of living." *See id.* Indeed, Winslow himself exemplifies the use of cost data for these purposes by discussing the relative economic merits of preventative versus curative strategies. *See id.* at 28-29.

It is therefore significant that Winslow's public health definition is cited to this day in leading technical dictionaries. *See* Andrew Porteous, DICTIONARY OF ENVIRONMENTAL SCIENCE AND TECHNOLOGY 445 (2d ed. 1996) ("The basic definition of public health has been given by C.E.A. Winslow, THE COST OF SICKNESS AND THE PRICE OF HEALTH; *accord* Committee for the Study of the Future of Public Health, Division of Health Care Services, Institute of Medicine, THE

FUTURE OF PUBLIC HEALTH 39 (1988) (calling Winslow's definition "[o]ne of the earliest deliberate efforts to define public health's mission [and] still one of the most frequently cited"). Moreover, Winslow's concept of public health as considering costs through the synthesis of the medical and social sciences remains influential not just in works of reference, but also in the scholarly literature.[1]

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[1] *See* David R. Holtgrave *et al.*, *Human Immunodeficiency Virus Counseling, Testing, Referral, and Partner Notification Services, A Cost-Benefit Analysis*, 153 Arch. Intern. Med. (1993); Peter D. Jacobson, *et al.*, *Litigation and Public-Health Policy Making: The Case of Tobacco Control*, 24 J. Health Pol. Pol'y & L. 769, 800 (1999) ("In any given public health issue, the balance will vary depending on the nature and extent of the abridgment of individual liberties, the nature and costs of the public health intervention, the alternatives to governmental intervention, the voluntariness of the activity, and the extent of harm to third persons in the absence of governmental activity."); George C. Cunningham, *A Public Health Perspective on the Control of Predictive Screening for Breast Cancer*, 7 Health Matrix: J. of L.-Med. 31, 36 (1997) (breast cancer screenings must be cost-beneficial and cost-effective); Michael J. Malinkowski, *Globalization of Biotechnology and the Public Health Challenges Accompanying It*, 60 Alb. L. Rev. 119, 163 (1996) ("The myriad of biotechnology capabilities now reaching commerce cannot be made sufficiently available to maximize improvements to public health without cost-benefit analysis."); *Sustainable Redevelopment of Brownfields: Using Institutional Controls to Protect Public Health*, 29 E.L.R. 10243 (1999) ("Among the issues relevant to the effectiveness of institutional controls are how long the risk is expected to remain, how many people may be exposed, potential exposure pathways, whether children may be exposed, how the population may change during the life of the risk, the cost of implementing the control, and the health and safety consequences of exposure."); Lawrence O. Gostin, *et al.*, *The Law and the Public's Health: A Study of Infectious Disease Law in the United States*, 99 Colum. L. Rev. 59, 128 (1999) ("Public health law reform should promote public health goals by mandating cost-effective alternatives"); Wendy E. Parmett, *Tobacco, HIV, and the Courtroom: The Role of Affirmative Litigation in the Formation of Public Health Policy*, 36 Hous. L. Rev. 1663, 1687 & n.147 (1999) ("classic model of public health law" considers a form of cost-benefit analysis); Lawrence O. Gostin & Zita Lazzarini, *Prevention of HIV/AIDS*

(continued...)

Although it is surely impossible to elicit a single formulation of what it means to "protect public health," there can be no doubt that the phrase has long connoted a sensitivity to comparative costs and benefits. Indeed, it may be possible to generalize from the academic literature that "[p]ublic health interventions should be based on the degree of risk, *the cost and efficacy of the response*, and the burden on human rights." Lawrence O. Gostin & James G. Hodge, Jr., *The Public Health Improvement Process in Alaska: Toward a Model Public Health Law*, 17 Alaska L. Rev. 77, 83 (2000) (emphasis added). But whatever precise formulation of the role of costs and similar considerations is chosen, the fact remains that the practice of modern "public health" means that these factors, at a minimum, must be considered. Indeed, this Court itself recently recognized in a different context that Congress could not have intended health concerns to exclude all consideration of cost, since the determination what degree of "risk" is "unacceptabl[e]" necessarily "depend[s] on a judgment about the appropriate level of expenditure for health care in light of the associated . . . risk." *Pegram v. Herdrich*, 120 S. Ct. 2143, 2150 (2000). There is accordingly no way to reconcile the "ordinary and natural" meaning of "public health," *see Meyer*, 510 U.S. at 476, with *Lead Industries*' absolute bar on the consideration of such factors.

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[1] (...continued)
Among Injection Drug Users: The Theory and Science of Public Health and Criminal Justice Approaches to Disease Prevention, 46 Emory L.J. 587 (1997) ("the public health perspectiv[e] . . . readily lends itself to a consequentialist analysis," specifically, "weighing the benefits, costs, and harms generated by each approach, to determine which yields the greatest aggregate value").

B. The Supporting Provisions in Sections 108(a), 108(b) and 109(d) Confirm that Non-Health Factors, Including Compliance Costs, Are to Be Considered in Setting NAAQS.

The *Lead Industries* line of cases has never focused on the meaning of public health as outlined above. Those precedents seek instead to tease out a definition, not directly, but by negative implication from the fact that section 109(b)(1) directs that NAAQS be promulgated "based on such criteria," presumably meaning the criteria document described in section 108(a)(2). Section 108(a)(2) requires EPA to develop:

> Air quality criteria for an air pollutant [that] shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of *all identifiable effects on public health or welfare* which may be expected from the presence of such pollutant in the ambient air, in varying quantities.

CAA § 108(a)(2), 42 U.S.C. § 7408(a)(2) (emphasis added). The provision then sets forth, in its subparagraphs (A), (B), and (C), three specific types of material that a criteria document "*shall* include" "to the extent practicable": (A) "variable factors" which may alter the effects of the pollutant on "public heath or welfare;" (B) other "air pollutants" that "may interact" with the pollutant under study in the atmosphere "to produce an adverse effect on public health or welfare;" and (C) "any known or anticipated adverse effects on welfare." *Id.*

As an initial matter, Subparagraph (C) by its terms apparently contemplates that the criteria documents should go beyond public health (however defined) and include information on "any known or anticipated adverse effects on public welfare." "Welfare" is then defined by the Act to mean effects on "soils, water, crops vegetation, manmade materials, animals, wildlife, weather, visibility, and climate, damage to and deterioration of property . . . as well as effects on *economic*

values and on personal comfort and well-being." CAA § 302(h), 42 U.S.C. § 7602(h) (emphasis added). Under any straightforward reading of these texts, the criteria document must therefore *include* information on "adverse" effects on "economic values and personal comfort"—concepts that surely are broad enough to encompass non-health factors such as compliance costs. Of course, such data are essential for setting "secondary" NAAQS under section 109(b)(2). But nothing in either section 108 or section 109 limits the use of cost and similar data to the setting of "secondary" standards, or excludes such information from consideration in setting "primary" standards, such as those at issue here.

The D.C. Circuit has never addressed the text of section 108(a)(2)(C) except obliquely and in dictum. *See Motor & Equip. Mfrs. Ass'n v. EPA*, 627 F.2d 1095, 1117-18 (D.C. Cir. 1979) ("*MEMA*"). The D.C. Circuit's *MEMA* dictum suggests, however, that criteria documents need only assess those "welfare effects" attributable to airborne pollution itself, not welfare effects that attend NAAQS compliance. *See id.* at 1118 ("The terms 'public health and welfare' . . . encompass economic values, but only to reflect the economic costs of pollution, not the social costs of pollution control."). But that reading is contradicted by the immediately preceding text of section 108(a)(2), which says that "[a]ir quality criteria for an air pollutant shall accurately reflect . . . *all* identifiable effects on public health *or welfare* which may be expected *from the presence of such pollutant in the ambient air*, in varying quantities." CAA § 108(a)(2), 42 U.S.C. § 7408(a)(2) (emphasis added). This broad directive to assess "*all* identifiable effects" on "welfare" attributable to "the presence of such pollutant in the ambient air" is, of course, precisely the meaning which the *MEMA* court would give to the entirely separate statement in section 108(a)(2)(C). The *MEMA* dictum thus violates the "cardinal principle of statutory construction" that statutes must be read so as "to give effect, if possible, to

every clause and word of a statute." *Bennett v. Spear*, 520 U.S. 154, 173 (1997).

The D.C. Circuit also has assumed that section 108(a)(2) "outlines *the criteria*"—that is, the *exclusive* criteria—"on which air quality standards are to be based." *Vinyl Chloride*, 824 F.2d at 1159 (quoting *Lead Industries*, 647 F.2d at 1149 n.37) (emphasis added). But the text of section 109(b)(1) does not compel this reading and other provisions of sections 108 and 109 positively refute it. *First*, the D.C. Circuit's interpretation fails to read "criteria" in conjunction with the rest of the Act. Outside of the Clean Air Act, "criteria" can and often do refer to standards on which "a decision may be based." *See* WEBSTER'S NINTH NEW COLLEGIATE DICTIONARY 307 (9th ed. 1987). As used in section 108, however, "criteria" refers not to decisional standards, but to the compilations of information that the Act requires EPA to use in NAAQS standard-setting. EPA itself refers to each such compilation in capital letters as a "Criteria *Document*." *See, e.g.*, 62 Fed Reg. at 38,654 (PM rule); 62 Fed. Reg. at 38,857 (Ozone rule).

Second, a Criteria Document does not remotely establish the *exclusive* compendium of decisional information necessary for NAAQS standard-setting. The Act directs EPA to set standards "based on" criteria documents; it does *not* require that standards be "based *solely* on" criteria documents. Section 108 instead identifies information that criteria documents must "include," but are not necessarily limited to—the information listed in subparagraphs (A), (B), and (C) of section 108(a)(2). The Act then directs EPA to consider the Criteria Document *in conjunction with* other informational sources, including the "findings, recommendations and comments" of CASAC, CAA § 307(d)(3), 42 U.S.C. § 7607(d)(3), plus "written comments, data, or documentary information" submitted by the public, CAA § 307(d)(4)(B)(i), 42 U.S.C. § 7607(d)(4)(B)(i). Moreover, Congress plainly expected that all of these data—even those outside the Criteria Document—would be

part of the Administrator's decisionmaking data set. The Act thus expressly provides that EPA must respond to significant public "comments, criticism, and new data," CAA § 307(d)(6)(B), 42 U.S.C. § 7607(d)(6)(B), and offer "an explanation of the reasons" for departures from CASAC's recommendations. CAA § 307(d)(3), 42 U.S.C. § 7607(d)(3).

Congress also made plain that compliance cost data, again including data not contained in a Criteria Document, are among the types of information that EPA necessarily must consider. The 1970 amendments added not just section 109(b), but also an elaborated requirement in section 108(b) that EPA issue—"simultaneously" with the Criteria Document and *before* EPA opens a NAAQS rulemaking—"information" on the "cost" of "air pollution control techniques." CAA § 108(b)(1), 42 U.S.C. § 7408(b)(1). Section 108(b)(1) mandates that this cost information be provided to "states and appropriate air pollution control agencies," "announced in the Federal Register," and "made available to the general public." CAA § 108(d), 42 U.S.C. § 7408(d). Given the Act's extensive procedural provisions, the requirement that cost information be provided *simultaneously* with a criteria document means that it must be made available at least three or four years before States begin planning compliance with a revised NAAQS. In the meantime, EPA must provide time for CASAC review, issue a proposal to revise a NAAQS, promulgate a final NAAQS, and make area designations of compliance or non-compliance with the new standard. *See* CAA § 107(d), 42 U.S.C. § 7407(d). The self-evident purpose of section 108(b)(1)'s otherwise inexplicably premature mandate must be to equip States, localities, and others with the information needed to criticize EPA's consideration of compliance costs in NAAQS standard-setting proceedings. *Cf.* CAA § 307(d)(6)(B), 42 U.S.C. § 7607(d)(6)(B) (EPA required to "respond to significant" public "comments, criticism, *and new data*") (emphasis added).

If there were any doubt on this point, it was laid to rest by the 1977 Amendments, which added the requirement that CASAC "advise the Administrator" on both health considerations *and* countervailing factors, including "*any* adverse public health, welfare, *social, economic, or energy effects* which may result from various strategies for attainment and maintenance of" the NAAQS. CAA § 109(d)(2)(C)(iv), 42 U.S.C. § 7409(d)(2)(C)(iv) (emphasis added). EPA cannot seriously maintain that this required advice was to play no role in the setting of revised NAAQS, for the Act also expressly specifies that whenever EPA notices proposed NAAQS revisions, it must summarize "*any* pertinent findings, recommendations, and comments" by CASAC (including advice under section 109(d)(2)(C)(iv)), and justify any significant departures from CASAC's recommendations. CAA § 307(d)(3), 42 U.S.C. § 7607(d)(3) (emphasis added); *accord* H.R. Rep. 95-294, 95th Cong., 1st Sess. 10 (1977) ("In deciding whether revision or promulgation of a new standard is necessary, the Administrator must consider the advice of an independent scientific review committee.").

The court below incorrectly rejected this interpretation, however, claiming that section 109(d)(2)(C)(iv) is aimed largely at state officials and NAAQS implementation efforts. *See* Pet. App. 21a. But that reading is contradicted by both the provision's text and the statutory structure. Section 109(d)(2)(C)(iv) could not be clearer—the advice called for by that provision is to be given to "the Administrator," not to State officials. Moreover, section 109, by its terms, exclusively concerns the setting of NAAQS by the EPA Administrator. It is other sections of the Act, including section 110 and all of Subpart 2 of Part D of Title I, that govern NAAQS implementation by the States. Accordingly, both the plain language and the placement of section 109(d)(2)(C)(iv) compel the conclusion that CASAC's economic advice is intended to be used in setting NAAQS.

C. The Statutory Purpose Confirms that EPA Must Consider Non-Health Factors in Setting NAAQS.

Considering all of the above provisions "in light of" the Act's "purposes and legislative history," *Gulf Oil Corp. v. Copp Paving Co.*, 419 U.S. 186, 197 (1974), further reinforces the requirement that EPA engage in a commonsense weighing of benefits and costs. The first purpose of the Act, stated in section 101(b)(1), is "to protect and enhance the quality of the Nation's air resources *so as* to promote the public health and welfare and the productive capacity of its population." 42 U.S.C. § 7401(b)(1) (emphasis added). This statement of purpose underscores that NAAQS, the engine that drives the national pollution control program, must be geared to provide "public health" protection as traditionally defined. It also makes plain that the aim of the Act is *not* to protect the Nation's air resources for their own sake, but "*so as*" to "promote public health and welfare and *the productive capacity* of its population." *Id.* (emphasis added). This statement is a reminder that in the Clean Air Act, "public health and welfare" can never be divorced from "the productive capacity" upon which both necessarily depend.[2]

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[2] The legislative history reinforces this point. The 1970 committee reports do not directly address the question whether compliance costs should be considered in setting NAAQS, apparently because Congress simply assumed that benefits would dwarf those costs. A study in the Congressional Record thus estimates that air pollution imposed costs on the economy that "amount to many billions of dollars a year." Legislative History of the Clean Air Act Amendments of 1970, Vol. I at 248-49. The National Institute of Environmental Health further estimated "[t]he cost of environmentally induced disease" alone to be "*$38 billion* a year." *Id.* at 124 (emphasis added). By contrast, control costs were expected to total only *$2.6 billion* through 1975, plus an additional $1.9 billion in 1975, *id.* at 249—an estimate that in retrospect proved far too low. *See* Mark K. Landy, *et al.*, THE ENVIRONMENTAL PROTECTION AGENCY: ASKING THE WRONG QUESTIONS FROM NIXON TO CLINTON 67-70 (1994).

Given the Act's codified purpose and the traditional understanding of "public health," EPA is compelled to ask in each case whether its NAAQS will do more good than harm for public. The record here almost certainly produces a negative answer for ozone and, quite possibly, a negative answer for PM as well. EPA's ozone RIA, for example, shows that annual ozone compliance costs will exceed benefits by $1.1 billion to $8.1 billion for each year by 2010. RIA at ES-11, ES-17. By contrast, the high-end estimate of EPA's PM RIA purports to show net benefits. But, if CASAC's reservations about fine-particle mortality are credited, the predicted benefits fall to EPA's low-end estimate, which means that costs also exceed benefits for full attainment of the PM NAAQS. *See supra* at 19. Moreover, government officials outside EPA have uniformly faulted EPA's projected compliance costs for both ozone and PM as significantly understated. *See supra* at 11, 19. Finally, EPA's benefit estimates for both rules omit all offsets for health "disbenefits" of lower pollution levels, such as the diminished ground-level screening of ultra-violet radiation that OMB analysts project could be "similar in magnitude to the respiratory-related beneficial effects of [an ozone] reduction." OJA at 2759, 2764; *see also id.* at 3089; *supra* at 8-9.

III. EPA MAY ACTUALLY BE CONSIDERING NON-HEALTH FACTORS IN SETTING NAAQS WHILE USING *LEAD INDUSTRIES* AS A SHIELD AGAINST EXECUTIVE, CONGRESSIONAL AND JUDICIAL OVERSIGHT.

The history of past revisions to the ozone and PM standards shows that economic considerations almost inevitably play a role in setting NAAQS, and, equally significantly, that economic analyses can push decisionmakers in the direction of both more lenient standards (as in the 1979 ozone revisions) and more stringent ones (as in the 1987 PM revisions). In revising the ozone NAAQS in 1979, Administrator Costle admittedly took costs into account. In that case, the Regulatory

Analysis Review Group, established by a Carter Administration Executive Order, prepared detailed estimates of expected compliance costs assuming various NAAQS levels. *See* Mark K. Landy, *et al.*, THE ENVIRONMENTAL PROTECTION AGENCY: ASKING THE WRONG QUESTIONS FROM NIXON TO CLINTON 67-70 (1994). Despite EPA's interpretation that non-health factors were excluded from consideration, these estimates were carefully considered by Administrator Costle and were the centerpiece of heated debates between EPA and the Council of Economic Advisors over the appropriate level of a revised NAAQS. *Id.* at 70-73. Administrator Costle later admitted that the level he selected took into account both medical and economic considerations. *See* Wendy E. Wagner, *The Science Charade in Toxic Risk Regulation*, 95 Colum. L. Rev. 1613, 1641-43 (1995).

The story was much the same when EPA last revised the PM NAAQS in 1987, albeit with a twist. There, the EPA Office of Policy Analysis prepared a cost-benefit assessment that tended to support selecting the new PM NAAQS from the lower end of the range proposed by the Staff Paper. *See* Thomas O. McGarity, REINVENTING RATIONALITY 47-48 (1991). Administrator Ruckelshaus, while expressing consternation that "he could not consider the cost and benefit information," stated nonetheless that the RIA (which was an outgrowth of this earlier economics staff analysis) "played no role whatsoever in his decisionmaking process . . . because he declined to read it." *Id.* at 50, 61. Still, "the knowledge among lower-level work group participants and midlevel managers [of the cost-benefit analysis] no doubt increased their comfort with recommending that the Administrator choose an option from the low end of the range." *Id.* at 61.

In light of this history, it certainly would not be surprising if EPA staff (or even the Administrator herself) privately consulted the available economic studies in setting these revised NAAQS. Indeed, the D.C. Circuit reversed the

Administrator for running afoul of *Lead Industries* by relying on a "pragmatic" consideration—specifically, "administrative convenience"—in selecting PM_{10} as the indicator for coarse PM. *See* Pet. App. 52a-53a; *supra* at 17. The Administrator also relied expressly on "efficien[cy]" concerns in deciding to promulgate both an annual and a 24-hour NAAQS for $PM_{2.5}$. *See* 62 Fed. Reg. at 38,670; *supra* at 17. And simultaneously with the issuance of the NAAQS, the Administrator issued a "soft" $10,000 compliance-cost cap per ton of emissions reductions based on the RIA. *See* 62 Fed. Reg. at 38,429.

As demonstrated below, this suggestive evidence raises still more fundamental questions about the viability of *Lead Industries*. The possibility that the Administrator may have considered supposedly non-health factors here, coupled with the fact that EPA routinely reads analogous Clean Air Act provisions to *permit* consideration of such factors, counsels the utmost skepticism when confronting EPA's continuing embrace of *Lead Industries*. *See* Part III.A, *infra*. And even more important, *Lead Industries* improperly shields EPA's decisionmaking from otherwise applicable executive, congressional and judicial oversight mechanisms. *See* Part III.B, *infra*. These two points present further grounds for rejecting *Lead Industries*.

A. EPA Cannot Distinguish NAAQS Standard-Setting from Analogous Clean Air Act Provisions Where the Agency Has Successfully Argued that Non-Health Factors May Be Considered.

Notwithstanding *Lead Industries*, EPA has successfully argued that similarly worded Clean Air Act provisions permit consideration of supposedly non-health factors, most recently in *State of Michigan v. EPA*, No. 98-1497, 2000 WL 180650 (D.C. Cir. Mar. 3, 2000). *State of Michigan* involved an interstate pollution transport provision prohibiting "any air pollutant in amounts which will . . . contribute *significantly*" to nonattainment of the national standards. CAA

§ 7410(a)(2)(D)(i)(I); 42 U.S.C. § 7410(a)(2)(D)(i)(I) (emphasis added). EPA argued this provision allows it to require upwind States to impose "highly cost-effective controls," namely controls capable of removing NOx at "a cost of $2,000 or less per ton." 2000 WL 180650, at *8.

The D.C. Circuit accepted EPA's interpretation based on an analysis that began by posing the following question: "[C]an an agency sensibly decide whether a risk is '*significant*' without also examining the *cost* of eliminating it?" *Id.* at *11 (internal quotation omitted). The court then ruled: "It is only where there is a 'clear congressional intent to preclude consideration of cost' that we find agencies barred from considering costs." *Id.* at *12. Turning to the provision at issue, the court acknowledged that, like other provisions of the Act, it was "[a] mandate directed to some environmental benefit . . . phrased in general quantitative terms ('ample margin of safety,' 'substantial restoration,' and 'major'), [that] contains not a word alluding to non-health tradeoffs." *Id.* After discussing its precedents interpreting these provisions, the court concluded that "in each case we found that in making its judgments of degree the agency was free to consider the costs of demanding higher levels of environmental benefit. So too here." *Id.*

Nor is *State of Michigan* the first D.C. Circuit case to uphold EPA's authority to consider compliance costs under Clean Air Act provisions that aim to improve air quality. *George E. Warren v. EPA*, for example, upholds consideration of costs under the Act's anti-dumping provision, CAA § 211(k)(8), 42 U.S.C. § 7545(k)(8), which requires that conventional gasoline from each supplier remain as clean as it was in 1990. 159 F.3d 616, 623 (D.C. Cir. 1998). Similarly, *NRDC v. EPA* upholds EPA's use of a cost-benefit analysis in determining whether to add various categories of industrial sources to the list of "major" sources under the Act's "prevention of significant deterioration" provisions. 937 F.2d

641, 643 (D.C. Cir. 1991). And, of course, the D.C. Circuit, sitting *en banc* in *Vinyl Chloride*, has also upheld consideration of costs in setting "ample margins of safety" for hazardous air-pollutant limitations. 824 F.2d at 1154-58.

In short, EPA's bald assertion of a NAAQS exception to otherwise well-established interpretive practice is unavailing. Certainly, this claimed exception finds no support in the statutory context or text. *See* Parts I and II, *supra*. Moreover, even if the Act did not require that countervailing factors be considered, EPA still could not maintain that it is permitted to ignore those factors, given *Brown & Williamson* and similar decisions of this Court. *See supra* at 31-32.

B. Rejecting *Lead Industries* Will Help to Insure Effective Executive, Congressional and Judicial Oversight for NAAQS Standard-Setting.

The well-established Executive Branch mechanisms for overseeing agency rulemaking will work in the NAAQS context only if *Lead Industries* is rejected. For over twenty-five years, the Office of the President has overseen most major regulatory initiatives by requiring steps designed to ensure that such programs are cost-beneficial and cost-effective. President Clinton's Executive Order 12,866, like similar Orders from previous Presidents, is directly enforced by the Executive, not the Judiciary. *See* 58 Fed. Reg. 51,735, § 10 (Sept. 30, 1993). The stated "philosophy" of that Order is that "agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating." *Id.* § 1(a). "Costs and benefits shall be understood to include both quantifiable measures (to the fullest extent that these can be measured) and qualitative measures of costs and benefits that are difficult to quantify, but nevertheless essential to consider." *Id.*

Significantly, however, the Order provides that "in choosing among alternative regulatory approaches, agencies should select those approaches that maximize net benefits

(including potential economic, environmental, public health and safety, and other advantages; distributional impacts; and equity), *unless a statute requires another regulatory approach.*" *Id.* (emphasis added). This highlighted proviso is then elaborated in section 1(b), which provides that the agencies must adhere to these principles only "*to the extent permitted by law.*" Given this proviso, NAAQS standard-setting will enjoy a blanket exemption from Presidential regulatory oversight so long as *Lead Industries* is the law.

Lead Industries poses essentially the same problems for congressional regulatory oversight. In 1995, Congress enacted the Unfunded Mandates Reform Act ("UMRA"), 2 U.S.C. § 1501 *et seq.*, to "requir[e] that Federal agencies . . . consider estimates of the budgetary impact of regulations . . . upon State, local and tribal governments and the private sector." *Id.* § 1501(7)(B). Congress further directed that, in promulgating each major proposed rule, the agency prepare a document that includes "a qualitative and quantitative assessment of the anticipated costs and benefits of the Federal mandate," *id.* § 1532(a)(2); *see also id.* § 1511(a), and then select the "least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule," *id.* § 1535(a). As with Executive Order 12,866, however, UMRA's provisions, which are directly enforced by Congress, rather than the courts, apply only unless otherwise prohibited by law. *See id.* §§ 1532(a), 1535(b)(2). This exception likewise means that congressional oversight of NAAQS standard-setting under UMRA will not apply unless *Lead Industries* is rejected.

Lead Industries also threatens, for precisely the same reasons, the very foundations of effective judicial review. The Clean Air Act, like the APA, requires the Agency to engage in reasoned, non-arbitrary decisionmaking. *See* CAA § 307(d)(9), 42 U.S.C. § 7607(d)(9). Under this form of traditional rationality review, "[n]ot only must an agency's decreed result be within the scope of its lawful authority, but the process by

which it reaches that result must be logical and rational." *Allentown Mack Sales & Serv., Inc. v. NLRB*, 522 U.S. 359, 374 (1998). A necessary foundation for that review is the "strict and demanding requirement" that "an agency must cogently explain why it has exercised its discretion in a given manner." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 48 (1983). Otherwise, the courts could not begin to determine whether the agency had exercised its discretion in a reasoned manner, and "expertise, the strength of modern government, [would] become a monster which rules with no practical limits on its discretion." *Id.*

To the extent that EPA actually considers costs, while maintaining publicly that it does not, *Lead Industries* jeopardizes the fundamental presuppositions under which Congress delegates authority to EPA in the first instance. The "recognition of Congress' need to vest administrative agencies with [delegated authority] carries with it the correlative responsibility of the agency to explain the rationale and factual basis for its decision . . . ." *Bowen v. American Hosp. Ass'n*, 476 U.S. 610, 627 (1986) (plurality opinion). This requirement that agencies explain the actual basis for their decision "helps maintain public accountability" by exposing those decisions to public and congressional scrutiny. *See, e.g., American Med. Ass'n v. Reno*, 57 F.3d 1129, 1134 (D.C. Cir. 1995).

Finally, the alternative possibility that EPA truly is *not* considering costs runs afoul of a different reasoned decisionmaking requirement—the requirement that agencies undertake "consideration of the relevant factors" and "consider [each] important aspect of the problem." *State Farm*, 463 U.S. at 42. Non-health factors are "relevant" for NAAQS standard-setting for all of the statutory reasons detailed above. But it is not just the Clean Air Act itself that establishes their relevance; all of the most important decisionmakers in the NAAQS context have also deemed such factors critical to making the kind of hard choices that EPA necessarily must make in setting

NAAQS. That is true for EPA, as in *State of Michigan*, for President Clinton, as in Executive Order 12,866, and for Congress, as in the UMRA legislation.

UMRA is particularly instructive because it represents a *congressional* determination that costs are relevant, and thus should be considered under this Court's earlier decision in *State Farm*. As Judge Garland recently explained for the D.C. Circuit, the courts "may consider [such statutes] in determining whether EPA complied with the overall requirement that an agency's decisionmaking be neither arbitrary nor capricious," even though they are not judicially-enforceable in their own right. *Allied Local & Regional Mfrs. Caucus v. EPA*, No. 98-1526, 2000 WL 737750, at *16 (D.C. Cir. June 16, 2000) (interpreting UMRA and an analogous statute); *accord Thompson v. Clark*, 741 F.2d 401, 408 (D.C. Cir. 1984) (Scalia, J.) ("To say that an agency's compliance with [the statute] is not reviewable as such is not to say that the agency can ignore with impunity the effect of its rules").

In sum, the context, text, structure, and purpose of the Act, as well as related sources of law, all confirm that EPA must consider countervailing "non-health" factors in setting NAAQS. If there were any doubt on that score, however, nondelegation considerations would require that they be resolved in favor of considering costs and other countervailing factors. The reasons why the nondelegation doctrine independently requires that *Lead Industries* be repudiated will be explained in our next brief.

CONCLUSION

For the foregoing reasons, this Court should reverse the decision of the court of appeals to the extent that it precludes EPA from considering factors other than health effects relating to pollutants in the air, and order that court to vacate EPA's ozone and PM NAAQS and remand for EPA to reconsider its standards under a proper interpretation of the Act.

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APPENDIX

CAA § 101, 42 U.S.C. § 7401. Congressional findings and declaration of purpose

(a) Findings—

The Congress finds

(1) that the predominant part of the Nation's population is located in its rapidly expanding metropolitan and other urban areas, which generally cross the boundary lines of local jurisdictions and often extend into two or more States;

(2) that the growth in the amount and complexity of air pollution brought about by urbanization, industrial development, and the increasing use of motor vehicles, has resulted in mounting dangers to the public health and welfare, including injury to agricultural crops and livestock, damage to and the deterioration of property, and hazards to air and ground transportation;

(3) that air pollution prevention (that is, the reduction or elimination, through any measures, of the amount of pollutants produced or created at the source) and air pollution control at its source is the primary responsibility of States and local governments; and

(4) that Federal financial assistance and leadership is essential for the development of cooperative Federal, State, regional, and local programs to prevent and control air pollution.

(b) Declaration

The purposes of this subchapter are—

(1) to protect and enhance the quality of the Nation's air resources so as to promote the public health and welfare and the productive capacity of its population;

(2) to initiate and accelerate a national research and development program to achieve the prevention and control of air pollution;

(3) to provide technical and financial assistance to State and local governments in connection with the development and execution of their air pollution prevention and control programs; and

(4) to encourage and assist the development and operation of regional air pollution prevention and control programs.

(c) Pollution prevention

A primary goal of this chapter is to encourage or otherwise promote reasonable Federal, State, and local governmental actions, consistent with the provisions of this chapter, for pollution prevention.

CAA § 108, 42 U.S.C. § 7408. Air quality criteria and control techniques

(a) Air pollutant list; publication and revision by Administrator; issuance of air quality criteria for air pollutants

(1) For the purpose of establishing national primary and secondary ambient air quality standards, the Administrator shall within 30 days after December 31, 1970, publish, and shall from time to time thereafter revise, a list which includes each air pollutant—

(A) emissions of which, in his judgment, cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare;

(B) the presence of which in the ambient air results from numerous or diverse mobile or stationary sources; and

(C) for which air quality criteria had not been issued before December 31, 1970, but for which he plans to issue air quality criteria under this section.

(2) The Administrator shall issue air quality criteria for an air pollutant within 12 months after he has included such pollutant in a list under paragraph (1). Air quality criteria for an air pollutant shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air, in varying quantities. The criteria for an air pollutant, to the extent practicable, shall include information on—

(A) those variable factors (including atmospheric conditions) which of themselves or in combination with other factors may alter the effects on public health or welfare of such air pollutant;

(B) the types of air pollutants which, when present in the atmosphere, may interact with such pollutant to produce an adverse effect on public health or welfare; and

(C) any known or anticipated adverse effects on welfare.

(b) Issuance by Administrator of information on air pollution control techniques; standing consulting committees for air pollutants; establishment; membership

(1) Simultaneously with the issuance of criteria under subsection (a) of this section, the Administrator shall, after consultation with appropriate advisory committees and Federal departments and agencies, issue to the States and appropriate air pollution control agencies information on air pollution control techniques, which information shall include data relating to the cost of installation and operation, energy requirements, emission reduction benefits, and environmental impact of the emission control technology. Such information shall include such data as are available on available technology

and alternative methods of prevention and control of air pollution. Such information shall also include data on alternative fuels, processes, and operating methods which will result in elimination or significant reduction of emissions.

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CAA § 109, 42 U.S.C. § 7409. National primary and secondary ambient air quality standards

(a) Promulgation

(1) The Administrator—

(A) within 30 days after December 31, 1970, shall publish proposed regulations prescribing a national primary ambient air quality standard and a national secondary ambient air quality standard for each air pollutant for which air quality criteria have been issued prior to such date; and

(B) after a reasonable time for interested persons to submit written comments thereon (but no later than 90 days after the initial publication of such proposed standards) shall by regulation promulgate such proposed national primary and secondary ambient air quality standards with such modifications as he deems appropriate.

(2) With respect to any air pollutant for which air quality criteria are issued after December 31, 1970, the Administrator shall publish, simultaneously with the issuance of such criteria and information, proposed national primary and secondary ambient air quality standards for any such pollutant. The procedure provided for in paragraph (1)(B) of this subsection shall apply to the promulgation of such standards.

(b) Protection of public health and welfare

(1) National primary ambient air quality standards, prescribed under subsection (a) of this section shall be ambient

air quality standards the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health. Such primary standards may be revised in the same manner as promulgated.

(2) Any national secondary ambient air quality standard prescribed under subsection (a) of this section shall specify a level of air quality the attainment and maintenance of which in the judgment of the Administrator, based on such criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of such air pollutant in the ambient air. Such secondary standards may be revised in the same manner as promulgated.

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(d) Review and revision of criteria and standards; independent scientific review committee; appointment; advisory functions

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(2)(A) The Administrator shall appoint an independent scientific review committee composed of seven members including at least one member of the National Academy of Sciences, one physician, and one person representing State air pollution control agencies.

(B) Not later than January 1, 1980, and at five-year intervals thereafter, the committee referred to in subparagraph (A) shall complete a review of the criteria published under section 7408 of this title and the national primary and secondary ambient air quality standards promulgated under this section and shall recommend to the Administrator any new national ambient air quality standards and revisions of existing criteria and standards as may be appropriate under section 7408 of this title and subsection (b) of this section.

(C) Such committee shall also (i) advise the Administrator of areas in which additional knowledge is required to appraise the adequacy and basis of existing, new, or revised national ambient air quality standards, (ii) describe the research efforts necessary to provide the required information, (iii) advise the Administrator on the relative contribution to air pollution concentrations of natural as well as anthropogenic activity, and (iv) advise the Administrator of any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such national ambient air quality standards.

CAA § 307, 42 U.S.C. § 7607. Administrative proceedings and judicial review

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(d) Rulemaking

(1) This subsection applies to—

(A) the promulgation or revision of any national ambient air quality standard under section 7409 of this title,

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(3) In the case of any rule to which this subsection applies, notice of proposed rulemaking shall be published in the Federal Register, as provided under section 553(b) of Title 5, shall be accompanied by a statement of its basis and purpose and shall specify the period available for public comment (hereinafter referred to as the "comment period"). The notice of proposed rulemaking shall also state the docket number, the location or locations of the docket, and the times it will be open to public inspection. The statement of basis and purpose shall include a summary of—

(A) the factual data on which the proposed rule is based;

(B) the methodology used in obtaining the data and in analyzing the data; and

(C) the major legal interpretations and policy considerations underlying the proposed rule.

The statement shall also set forth or summarize and provide a reference to any pertinent findings, recommendations, and comments by the Scientific Review Committee established under section 7409(d) of this title and the National Academy of Sciences, and, if the proposal differs in any important respect from any of these recommendations, an explanation of the reasons for such differences. All data, information, and documents referred to in this paragraph on which the proposed rule relies shall be included in the docket on the date of publication of the proposed rule.

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(5) In promulgating a rule to which this subsection applies (i) the Administrator shall allow any person to submit written comments, data, or documentary information . . . .

(6)(A) The promulgated rule shall be accompanied by (i) a statement of basis and purpose like that referred to in paragraph (3) with respect to a proposed rule and (ii) an explanation of the reasons for any major changes in the promulgated rule from the proposed rule.

(B) The promulgated rule shall also be accompanied by a response to each of the significant comments, criticisms, and new data submitted in written or oral presentations during the comment period.

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Unfunded Mandates Reform Act, 2 U.S.C. § 1501. Purposes

The purposes of this chapter are—

(1) to strengthen the partnership between the Federal Government and State, local, and tribal governments;

(2) to end the imposition, in the absence of full consideration by Congress, of Federal mandates on State, local, and tribal governments without adequate Federal funding, in a manner that may displace other essential State, local, and tribal governmental priorities;

(3) to assist Congress in its consideration of proposed legislation establishing or revising Federal programs containing Federal mandates affecting State, local, and tribal governments, and the private sector by—

(A) providing for the development of information about the nature and size of mandates in proposed legislation; and

(B) establishing a mechanism to bring such information to the attention of the Senate and the House of Representatives before the Senate and the House of Representatives vote on proposed legislation;

(4) to promote informed and deliberate decisions by Congress on the appropriateness of Federal mandates in any particular instance;

(5) to require that Congress consider whether to provide funding to assist State, local, and tribal governments in complying with Federal mandates, to require analyses of the impact of private sector mandates, and through the dissemination of that information provide informed and deliberate decisions by Congress and Federal agencies and retain competitive balance between the public and private sectors;

(6) to establish a point-of-order vote on the consideration in the Senate and House of Representatives of legislation containing significant Federal intergovernmental

mandates without providing adequate funding to comply with such mandates;

(7) to assist Federal agencies in their consideration of proposed regulations affecting State, local, and tribal governments, by—

(A) requiring that Federal agencies develop a process to enable the elected and other officials of State, local, and tribal governments to provide input when Federal agencies are developing regulations; and

(B) requiring that Federal agencies prepare and consider estimates of the budgetary impact of regulations containing Federal mandates upon State, local, and tribal governments and the private sector before adopting such regulations, and ensuring that small governments are given special consideration in that process; and

(8) to begin consideration of the effect of previously imposed Federal mandates, including the impact on State, local, and tribal governments of Federal court interpretations of Federal statutes and regulations that impose Federal intergovernmental mandates.

Unfunded Mandates Reform Act, 2 U.S.C. § 1511. Cost of regulations

(a) Sense of the Congress

It is the sense of the Congress that Federal agencies should review and evaluate planned regulations to ensure that the cost estimates provided by the Congressional Budget Office will be carefully considered as regulations are promulgated.

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2 U.S.C. § 1532. Statements to accompany significant regulatory actions

(a) In general

Unless otherwise prohibited by law, before promulgating any general notice of proposed rulemaking that is likely to result in promulgation of any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year, and before promulgating any final rule for which a general notice of proposed rulemaking was published, the agency shall prepare a written statement containing—

(1) an identification of the provision of Federal law under which the rule is being promulgated;

(2) a qualitative and quantitative assessment of the anticipated costs and benefits of the Federal mandate, including the costs and benefits to State, local, and tribal governments or the private sector, as well as the effect of the Federal mandate on health, safety, and the natural environment and such an assessment shall include—

(A) an analysis of the extent to which such costs to State, local, and tribal governments may be paid with Federal financial assistance (or otherwise paid for by the Federal Government); and

(B) the extent to which there are available Federal resources to carry out the intergovernmental mandate;

(3) estimates by the agency, if and to the extent that the agency determines that accurate estimates are reasonably feasible, of—

(A) the future compliance costs of the Federal mandate; and

(B) any disproportionate budgetary effects of the Federal mandate upon any particular regions of the nation or particular State, local, or tribal governments, urban or rural or other types of communities, or particular segments of the private sector;

(4) estimates by the agency of the effect on the national economy, such as the effect on productivity, economic growth, full employment, creation of productive jobs, and international competitiveness of United States goods and services, if and to the extent that the agency in its sole discretion determines that accurate estimates are reasonably feasible and that such effect is relevant and material; and

(5)(A) a description of the extent of the agency's prior consultation with elected representatives (under section 1534 of this title) of the affected State, local, and tribal governments;

(B) a summary of the comments and concerns that were presented by State, local, or tribal governments either orally or in writing to the agency; and

(C) a summary of the agency's evaluation of those comments and concerns.

(b) Promulgation

In promulgating a general notice of proposed rulemaking or a final rule for which a statement under subsection (a) of this section is required, the agency shall include in the promulgation a summary of the information contained in the statement.

(c) Preparation in conjunction with other statement

Any agency may prepare any statement required under subsection (a) of this section in conjunction with or as a part of any other statement or analysis, provided that the statement or analysis satisfies the provisions of subsection (a) of this section.

§ 1535. Least burdensome option or explanation required

(a) In general

Except as provided in subsection (b) of this section, before promulgating any rule for which a written statement is required under section 1532 of this title, the agency shall identify and consider a reasonable number of regulatory alternatives and from those alternatives select the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule, for—

(1) State, local, and tribal governments, in the case of a rule containing a Federal intergovernmental mandate; and

(2) the private sector, in the case of a rule containing a Federal private sector mandate.

(b) Exception

The provisions of subsection (a) of this section shall apply unless—

(1) the head of the affected agency publishes with the final rule an explanation of why the least costly, most cost-effective or least burdensome method of achieving the objectives of the rule was not adopted; or

(2) the provisions are inconsistent with law.

(c) OMB certification

No later than 1 year after March 22, 1995, the Director of the Office of Management and Budget shall certify to Congress, with a written explanation, agency compliance with this section and include in that certification agencies and rulemakings that fail to adequately comply with this section.

Executive Order 12866, 58 Fed. Reg. 51,735 (Sept. 30, 1993)

Regulatory Planning and Review

The American people deserve a regulatory system that works for them, not against them: a regulatory system that protects and improves their health, safety, environment, and well-being and improves the performance of the economy without imposing unacceptable or unreasonable costs on society; regulatory policies that recognize that the private sector and private markets are the best engine for economic growth; regulatory approaches that respect the role of State, local, and tribal governments; and regulations that are effective, consistent, sensible, and understandable. We do not have such a regulatory system today.

With this Executive Order, the Federal Government begins a program to reform and make more efficient the regulatory process. The objectives of this Executive order are to enhance planning and coordination with respect to both new and existing regulations; to reaffirm the primacy of Federal agencies in the regulatory decision-making process; to restore the integrity and legitimacy of regulatory review and oversight; and to make the process more accessible and open to the public. In pursuing these objectives, the regulatory process shall be conducted so as to meet applicable statutory requirements and with due regard to the discretion that has been entrusted to the Federal agencies.

Accordingly, by the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. Statement of Regulatory Philosophy and Principles.

(a) The Regulatory Philosophy. Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public need, such as material failures of private

markets to protect or improve the health and safety of the public, the environment, or the well-being of the American people. In deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating. Costs and benefits shall be understood to include both quantifiable measures (to the fullest extent that these can be usefully estimated) and qualitative measures of costs and benefits that are difficult to quantify, but nevertheless essential to consider. Further, in choosing among alternative regulatory approaches, agencies should select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity), unless a statute requires another regulatory approach.

(b) The Principles of Regulation. To ensure that the agencies' regulatory programs are consistent with the philosophy set forth above, agencies should adhere to the following principles, to the extent permitted by law and where applicable:

(1) Each agency shall identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem.

(2) Each agency shall examine whether existing regulations (or other law) have created, or contributed to, the problem that a new regulation is intended to correct and whether those regulations (or other law) should be modified to achieve the intended goal of regulation more effectively.

(3) Each agency shall identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public.

(4) In setting regulatory priorities, each agency shall consider, to the extent reasonable, the degree and nature of the risks posed by various substances or activities within its jurisdiction.

(5) When an agency determines that a regulation is the best available method of achieving the regulatory objective, it shall design its regulations in the most cost-effective manner to achieve the regulatory objective. In doing so, each agency shall consider incentives for innovation, consistency, predictability, the costs of enforcement and compliance (to the government, regulated entities, and the public), flexibility, distributive impacts, and equity.

(6) Each agency shall assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.

(7) Each agency shall base its decisions on the best reasonably obtainable scientific, technical, economic, and other information concerning the need for, and consequences of, the intended regulation.

(8) Each agency shall identify and assess alternative forms of regulation and shall, to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt.

(9) Wherever feasible, agencies shall seek views of appropriate State, local, and tribal officials before imposing regulatory requirements that might significantly or uniquely affect those governmental entities. Each agency shall assess the effects of Federal regulations on State, local, and tribal governments, including specifically the availability of resources to carry out those mandates, and seek to minimize those burdens that uniquely or significantly affect such governmental entities, consistent with achieving regulatory objectives. In

addition, as appropriate, agencies shall seek to harmonize Federal regulatory actions with related State, local, and tribal regulatory and other governmental functions.

(10) Each agency shall avoid regulations that are inconsistent, incompatible, or duplicative with its other regulations or those of other Federal agencies.

(11) Each agency shall tailor its regulations to impose the least burden on society, including individuals, businesses of differing sizes, and other entities (including small communities and governmental entities), consistent with obtaining the regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations.

(12) Each agency shall draft its regulations to be simple and easy to understand, with the goal of minimizing the potential for uncertainty and litigation arising from such uncertainty.

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Section 10. Judicial Review.

Nothing in this Executive order shall affect any otherwise available judicial review of agency action. This Executive order is intended only to improve the internal management of the Federal Government and does not create any right or benefit, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies or instrumentalities, its officers or employees, or any other person.

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